APPENDIX A — OPINION OF THE UNITED STATES COURT OF APPEALS FOR THE SECOND CIRCUIT DECIDED OCTOBER 16, 2009

UNITED STATES COURT OF APPEALS FOR THE SECOND CIRCUIT

Docket No. 06-5525-cv

In Re: DDAVP DIRECT PURCHASER ANTITRUST LITIGATION,

Meijer, Inc., Meijer Distribution, Inc., on behalf of themselves and all others similarly situated,

Plaintiffs-Appellants,

Rochester Drug Co-Operative, Inc., Louisiana Wholesale Drug Co., Inc.,

Consolidated-Plaintiffs-Appellants,

— v. —

Ferring B.V., Ferring Pharmaceuticals, Inc., Aventis Pharmaceuticals, Inc.,

Defendants-Appellees,

Appendix A

— v. —

Vista Healthplan, Inc., on behalf of itself and all others, Pennsylvania Employees Benefit Trust Fund, on behalf of itself and all others, Painters District Council No. 30 Health and Welfare Fund, Philadelphia Federation of Teachers Health and Welfare Fund,

Consolidated Plaintiffs.

Argued: Sept. 15, 2008.

Decided: Oct. 16, 2009.

Before: FEINBERG, WALKER, and LIVINGSTON, Circuit Judges.

JOHN M. WALKER, JR., Circuit Judge:

This case presents a novel question of standing that lies at the junction of antitrust and patent law. The plaintiffs, direct purchasers of desmopressin acetate tablets (sold under the name DDAVP), filed this class action in the Southern District of New York (Charles L. Brieant, *Judge*) against the defendants Ferring B.V., Ferring Pharmaceuticals (collectively, "Ferring"), and Aventis Pharmaceuticals ("Aventis"), alleging that Ferring and Aventis abused the patent system to unlawfully maintain a monopoly over DDAVP. Ferring developed, patented, and manufactures DDAVP, and Aventis holds FDA approval for DDAVP tablets as well

as a license from Ferring to market and sell the drug. The plaintiffs alleged that Ferring and Aventis inflated the price of DDAVP by suppressing generic competition for the tablets in violation of the antitrust laws. The district court dismissed the suit, concluding that the plaintiffs both lacked antitrust standing and had failed to state a claim upon which relief could be granted. This appeal followed.

BACKGROUND

The facts that follow are either undisputed or, because they are properly pled, presumed true for the purposes of this appeal at the pleading stage. *See Diaz v. Paterson*, 547 F.3d 88, 91 (2d Cir. 2008).

DDAVP is an antidiuretic prescription medication used to manage a form of diabetes, excessive urination, excessive thirst, and bed wetting. Ferring developed and manufactures DDAVP and owns U.S. Patent No. 5,047,398 (the "'398 patent"), which claims the compound in tablet form. Ferring filed its application for the '398 patent on December 17, 1985, and the Patent and Trade Office ("PTO") issued the patent on September 10, 1991. Ferring granted an exclusive license to Aventis to market and sell the patented tablets under the DDAVP name. In addition to its license from Ferring, Aventis also holds an approved New Drug Application ("NDA") from the FDA for the tablets. A manufacturer seeking to market a new drug must file an NDA to demonstrate the drug's safety and efficacy.

Appendix A

In 2002, Ferring filed a patent infringement suit against Barr Laboratories, Inc. ("Barr"), which came before the same district judge who later presided over this action. Earlier that year, Barr had filed an Abbreviated New Drug Application ("ANDA") for a generic version of the compound. An ANDA filing accelerates the approval process for a generic drug by allowing the manufacturer to rely on the safety and efficacy data provided in the NDA for the drug's branded counterpart. As part of the ANDA, Barr filed a certification (called a "paragraph IV certification") stating that the '398 patent was invalid, unenforceable, and/or would not be infringed by Barr's generic product. This filing triggered Ferring's infringement action against Barr pursuant to 35 U.S.C. § 271(e)(2).

Ferring's suit failed. On summary judgment, the district court found that the '398 patent, rather than having been infringed by Barr, was unenforceable due to inequitable conduct before the PTO by Ferring and its agents. *Ferring B.V. v. Barr Labs., Inc.*, No. 7:02-CV-9851, 2005 U.S. Dist. LEXIS 3597, 2005 WL 437981, at *10 (S.D.N.Y. Feb. 7, 2005). The Federal Circuit affirmed. *See Ferring B.V. v. Barr Labs., Inc.* ("*Ferring I*"), 437 F.3d 1181 (Fed. Cir. 2006).

The inequitable conduct that crippled the '398 patent occurred on the patent's troubled path to approval. In November 1986, PTO examiners rejected certain of the '398 patent's claims as anticipated by or obvious from U.S. Patent No. 3,497,491 (the "'491 patent"), a patent exclusively licensed to Ferring that

subsequently expired in 1987. *See id.* at 1183-84. The Board of Patent Appeals and Interferences ("BPAI") affirmed the examiners' rejection in September 1990, but on slightly different grounds: relying only on the '491 patent, the BPAI concluded that the '491 patent rendered the '398 patent "obvious" when considered "in light of" a 1973 article written by Ivan Vavra. *Id.* at 1184. In November 1990, in an effort to persuade the examiners of the '398 patent's novelty, the applicants, two Ferring employees who assigned their prospective patent rights to Ferring, submitted declarations from several scientists stating that the '491 patent and Vavra article did not suggest the '398 patent. *Id.* at 1185. It turned out, however, that four of the five declarants previously had either "been employed or had received research funds from Ferring," facts that the submissions failed to disclose to the PTO. *See id.* On the strength of these declarations, the earlier rejection notwithstanding, the PTO issued the '398 patent in September 1991. *See id.* at 1185, 1188-89. The district judge found this non-disclosure to be inequitable conduct in the Barr litigation, and determined the patent to be unenforceable. *See id.* at 1194-95.

Upon *de novo* review, the Federal Circuit held both that the undisclosed affiliations would have been material to the examiners' decision to issue the '398 patent, *see id.* at 1187-90, and that the evidence suggested that the affiants' previous relationships with Ferring were "deliberately concealed," *id.* at 1193. The Federal Circuit therefore concluded that the district court had not abused its discretion in finding inequitable conduct,

see id. at 1194-95, rendering the '398 patent unenforceable as against Barr and all other parties.

Less than two months after the Federal Circuit's February 2006 ruling, the direct purchaser plaintiffs filed the instant suit. The plaintiffs argue that the defendants' conduct, in addition to making the '398 patent unenforceable, violated the antitrust laws. They allege that defendants Ferring and Aventis "engaged in an exclusionary scheme" that included (1) "[p]rocuring the '398 patent by committing fraud and/or engaging in inequitable conduct before the PTO," (2) "[i]mproperly listing the fraudulently obtained '398 patent in the [FDA's] Orange Book," thereby enabling patent infringement claims against potential competitors, (3) prosecuting sham infringement litigation against generic competitors, and (4) "filing a sham citizen petition to further delay FDA final approval of Barr's ANDA." Compl. ¶ 144. The plaintiffs claim that the lack of competing, generic versions of DDAVP injured them by forcing them to pay monopolistic prices for the drug.

Ferring and Aventis jointly moved to dismiss the complaint on the basis that, *inter alia*, the plaintiffs lacked standing to assert their claimed antitrust violations. Aventis separately moved to dismiss the case on the ground that the plaintiffs had not sufficiently alleged misconduct against it. The district court granted both motions and dismissed the antitrust action. *See In re DDAVP Direct Purchaser Antitrust Litig.*, No. 05 Cv. 2237, 2006 U.S. Dist. LEXIS 96201, *8 (S.D.N.Y. Nov. 2, 2006).

The district court acknowledged that, while conduct in obtaining and enforcing a patent is generally protected from antitrust liability by the First Amendment, a patentee loses this immunity and can incur antitrust liability for enforcing a patent if the patent was obtained by fraud on the PTO. *See id.* at 5-6 (citing *Walker Process Equip., Inc. v. Food Mach. & Chem. Corp.*, 382 U.S. 172, 173, 86 S. Ct. 347, 15 L. Ed. 2d 247 (1965)). However, the district court held that the plaintiffs failed to plead fraud on the PTO with sufficient particularity, noting that fraud requires a greater showing of culpability than the inequitable conduct that can render a patent unenforceable. *See id.* at 7-8. The district court concluded that, "[f]or this reason alone, granting the motions to dismiss is appropriate." *Id.* at 8.

However, "in the interest of completeness," the district court also considered the plaintiffs' standing. *Id.* As an initial matter, the district court noted the lack of binding precedent "with regard to the specific issue of whether purchaser plaintiffs like those in this case have standing to assert a *Walker Process* claim." *Id.* at 10-11. The district court then held that the plaintiffs lacked antitrust standing for their *Walker Process* claim because the '398 patent had not been enforced against them, and they were not competitors of Ferring or Aventis. *Id.* at 11-12 (citing *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 363 F. Supp. 2d 514 (E.D.N.Y. 2005); *Walgreen Co. v. Organon, Inc. (In re Remeron Antitrust Litig.)*, 335 F. Supp. 2d 522 (D.N.J. 2004)).

With little discussion, the district court also rejected the plaintiffs' non-*Walker Process* claims — the Orange Book listing, the sham infringement litigation, and the sham citizen's petition — on the basis that the defendants had not acted "in subjective bad faith." *Id.* at 13. Finally, the district court granted Aventis's separate motion to dismiss, concluding that the plaintiffs had failed to sufficiently allege that Aventis was complicit in Ferring's fraud upon the PTO. *Id.* at 14-15.

The plaintiffs now appeal the district court's decision in its entirety. They argue that the district court erred in dismissing the complaint and, in doing so, violated their due process rights. The defendants moved in this court to transfer the case on the basis that the Federal Circuit has exclusive jurisdiction over this appeal. We reserved decision on that motion.

DISCUSSION

I. Jurisdiction

We disagree that this appeal properly belongs in the Federal Circuit. The Federal Circuit has exclusive jurisdiction over appeals where the district court's jurisdiction is "based, in whole or in part, on section 1338 of [title 28]," 28 U.S.C. § 1295(a)(1), which in turn gives district courts "original jurisdiction of any civil action arising under any Act of Congress relating to patents," *id.* § 1338(a). Such jurisdiction exists if a case "arises under" patent law, such that "a well-pleaded complaint establishes either [1] that federal patent law creates the

cause of action or," as is relevant here, "[2] that the plaintiff's right to relief necessarily depends on resolution of a substantial question of federal patent law, in that patent law is a necessary element of one of the well-pleaded claims." *Christianson v. Colt Indus. Operating Corp.*, 486 U.S. 800, 808-09, 108 S. Ct. 2166, 100 L. Ed. 2d 811 (1988). However, "as long as there is at least one alternative theory supporting the claim that does not rely on patent law, there is no 'arising under' jurisdiction under 28 U.S.C. § 1338." *In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d 187, 199 (2d Cir. 2006). In such a scenario, because "there are reasons completely unrelated to the provisions and purposes of federal patent law why petitioners may or may not be entitled to the relief they seek under their monopolization claim, the claim does not arise under federal patent law." *Id.* (quoting *Christianson*, 486 U.S. at 812).

In this case, because the plaintiffs have filed an antitrust suit, patent law does not create the cause of action. The Federal Circuit's jurisdiction over this case, if it exists, must rest upon the second part of the *Christianson* test: that "the plaintiff's right to relief necessarily depends on resolution of a substantial question of federal patent law." 486 U.S. at 809. The plaintiffs argue that their right to relief can stand on any one of four different theories: (1) the defendants committed *Walker Process* fraud in obtaining and securing the '398 patent; (2) the defendants listed the '398 patent in the FDA's Orange Book despite knowing the patent was fraudulently procured and therefore

invalid; (3) the defendants, knowing the '398 patent was invalid, prosecuted sham patent infringement litigation against generic competitors in order to delay FDA approval of the competitors' generic DDAVP equivalent; and (4) the defendants filed a sham citizen petition, asking the FDA to require additional testing of a generic DDAVP equivalent (thus delaying its approval) despite knowing that such testing was unnecessary.

The first three of the plaintiffs' four theories plainly "depend[] on resolution of a substantial question of federal patent law," as they all turn on how the '398 patent was procured. In the absence of any fraud, actions taken by Ferring and Aventis in obtaining, maintaining, and enforcing the '398 patent would be exempt from antitrust liability. *See Walker Process*, 382 U.S. at 177 & n.5; *SCM Corp. v. Xerox Corp.*, 645 F.2d 1195, 1206 (2d Cir. 1981). The plaintiffs' antitrust claim, under their first three theories, requires that the '398 patent had been fraudulently procured. *See Walker Process*, 382 U.S. at 177 & n.5. In this context, fraud requires (1) a false representation or deliberate omission of a fact material to patentability, (2) made with the intent to deceive the patent examiner, (3) on which the examiner justifiably relied in granting the patent, (4) but for which misrepresentation or deliberate omission the patent would not have been granted. *See C.R. Bard, Inc. v. M3 Sys., Inc.*, 157 F.3d 1340, 1364 (Fed. Cir. 1998). Materiality, justifiable reliance, and but-for causation each implicate the issue of patentability, namely, whether the patent would have been granted in the absence of the fraudulent representations or

omissions. Because the first three theories turn on substantial questions of patent law, appellate jurisdiction would lie exclusively with the Federal Circuit if the plaintiffs' success solely depended on one or more of these theories.

The plaintiffs' fourth theory, however, does not turn on a substantial question of patent law. Under this theory, Ferring violated the antitrust laws when it filed a sham citizen petition with the FDA, requesting that the FDA require Barr to conduct extra testing to establish that its generic product was bioequivalent to DDAVP, thereby delaying approval of Barr's ANDA. Generally, under the *Noerr-Pennington* doctrine, citizen petitions are immune from antitrust liability in light of the First Amendment. *See E.R.R. Presidents Conference v. Noerr Motor Freight, Inc.*, 365 U.S. 127, 136, 81 S. Ct. 523, 5 L. Ed. 2d 464 (1961) ("[T]he Sherman Act does not prohibit two or more persons from associating together in an attempt to persuade the legislature or the executive to take particular action with respect to a law that would produce a restraint or a monopoly."); *United Mine Workers of Am. v. Pennington*, 381 U.S. 657, 670, 85 S. Ct. 1585, 14 L. Ed. 2d 626 (1965) ("Joint efforts to influence public officials do not violate the antitrust laws even though intended to eliminate competition."); *Primetime 24 Joint Venture v. Nat'l Broad. Co.*, 219 F.3d 92, 99 (2d Cir. 2000) (explaining that "concerted actions before courts and administrative agencies" are generally shielded from the Sherman Act by "the right to petition the legislature")

(citing *Cal. Motor Transp. Co. v. Trucking Unlimited*, 404 U.S. 508, 510-11, 92 S. Ct. 609, 30 L. Ed. 2d 642 (1972)).

Noerr-Pennington protection is not absolute, however. When petitioning activity "ostensibly directed toward influencing governmental action[] is a . . . sham to cover what is . . . nothing more than an attempt to interfere directly with the business relationships of a competitor[, then] the application of the Sherman Act would be justified." *Noerr*, 365 U.S. at 144. This sham exception requires that the petition be "(i) 'objectively baseless,' and (ii) 'an attempt to interfere directly with the business relationships of a competitor through the use of the governmental process — as opposed to the outcome of that process — as an anticompetitive weapon.'" *Primetime 24*, 219 F.3d at 100-01 (quoting *Prof'l Real Estate Investors, Inc. v. Columbia Pictures Indus., Inc.* ("*PRE*"), 508 U.S. 49, 60, 113 S. Ct. 1920, 123 L. Ed. 2d 611 (1993)).

The plaintiffs claim that the citizen petition was a sham because its sole purpose was "to delay the entry of generic competitors into the market." Compl. ¶ 105. Whether the petition was a sham is an issue independent of patent law; the substance of Ferring's citizen petition did not rest on the issuance or validity of a patent. A single lawsuit can violate antitrust law as long as it is both an objective and subjective sham. *BE&K Constr. Co. v. NLRB*, 536 U.S. 516, 526, 122 S. Ct. 2390, 153 L. Ed. 2d 499 (2002); *see also Tamoxifen*, 466 F.3d at 213 (citing *PRE*, 508 U.S. at 60). Administrative petitions,

while less susceptible than lawsuits to the sham exception, still carry the potential for antitrust liability. *See Kottle v. Nw. Kidney Ctrs.*, 146 F.3d 1056, 1062 (9th Cir. 1998) (noting that "the exact scope of the sham exception to the *Noerr-Pennington* doctrine has not always been clear in the administrative context" but finding it applicable to "a sufficiently circumscribed form of administrative authority" that is not "essentially political").

The fact that a single citizen petition may trigger the sham exception does not end our jurisdictional inquiry. Even if Ferring's citizen petition was a sham, "[p]roof of a sham merely deprives the defendant of immunity; it does not relieve the plaintiff of the obligation to establish all other elements of his claim." *PRE*, 508 U.S. at 61. Thus we must determine if any of these elements turn on a question of patent law, in which case the sham petition theory cannot be our basis for jurisdiction.

"[T]o state a claim for monopolization under Section 2 of the Sherman Act, a plaintiff must establish '(1) the possession of monopoly power in the relevant market and (2) the willful acquisition or maintenance of that power as distinguished from growth or development as a consequence of a superior product, business acumen, or historic accident.'" *PepsiCo, Inc. v. Coca-Cola Co.*, 315 F.3d 101, 105 (2d Cir. 2002) (per curiam) (quoting *United States v. Grinnell Corp.*, 384 U.S. 563, 570-71, 86 S. Ct. 1698, 16 L. Ed. 2d 778 (1966)). The plaintiffs also must demonstrate an antitrust injury and damages.

See Cordes & Co. Fin. Servs., Inc. v. A.G. Edwards & Sons, Inc., 502 F.3d 91, 105 (2d Cir. 2007).

The defendants argue that, because the citizen petition was filed over a year before the '398 patent was ruled unenforceable, the plaintiffs cannot prove the necessary intent to monopolize without showing that the patent was foreseeably unenforceable — an issue that raises questions of patent law. However, the '398 patent became unenforceable almost five months before the FDA rejected the citizen petition. During that time, the defendants were free to "supplement, amend, or withdraw" the petition, 21 C.F.R. § 10.30(g), which at that point they knew to be based upon an unenforceable patent. Even if the defendants' intent when filing the petition raises questions of patent law, their intent in maintaining the petition after they lost the infringement litigation does not. And because the defendants' failure to address the citizen petition after the '398 patent became unenforceable could plausibly constitute a Sherman Act violation, the citizen petition supports a patent-independent theory of liability. *See Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 566, 127 S. Ct. 1955, 167 L. Ed. 2d 929 (2007) (suggesting that either "action or inaction" could be plausibly alleged as an antitrust violation).

The failed infringement suit also dooms the defendants' suggestion that the '398 patent's status might impact the potential for antitrust injury from the citizen's petition. If the '398 patent had been valid, Barr's ANDA might have been denied regardless of the

citizen petition. But the '398 patent had already been held unenforceable due to inequitable conduct, and the ANDA denial was plainly not inevitable (as evidenced by its ultimate approval). Thus, the plaintiffs' antitrust claim can stand on the citizen petition theory without raising questions of patent law.

Finally, the defendants argue that jurisdiction properly lies with the Federal Circuit because the plaintiffs' citizen petition theory is a minor part of the overall allegations. Indeed, the plaintiffs themselves see the petition as only a single piece of a larger anticompetitive scheme of which the '398 patent is the linchpin. But the relief sought by the plaintiffs is not tied inextricably to this larger scheme. The plaintiffs simply ask for a judgment declaring the defendants' actions to have violated the Sherman Act. *See* Compl. 37-38. The question of whether the Federal Circuit has jurisdiction "focuses on claims, not theories, and just because an element that is essential to a particular theory might be governed by federal patent law does not mean that the entire monopolization claim 'arises under' patent law." *Christianson*, 486 U.S. at 811 (internal citations omitted). The defendants stress that the plaintiffs' patent-related theories are essential to the *overall* relief the plaintiffs seek, because the citizen petition theory covers a time period shorter than the overall allegations, but this fact lacks jurisdictional significance. Focusing on claims, not theories, we have jurisdiction as long as any one of the theories can support the claim without raising substantial questions

of patent law. The citizen petition theory satisfies this requirement, and therefore we have jurisdiction over this appeal.

II. Antitrust Standing

The defendants argue that the plaintiffs lack standing to pursue this action. We review questions of standing *de novo*. *Comer v. Cisneros*, 37 F.3d 775, 787 (2d Cir. 1994). In addition to demonstrating Article III standing, an antitrust plaintiff must also establish antitrust standing. *See Paycom Billing Servs., Inc. v. Mastercard Int'l, Inc.*, 467 F.3d 283, 290 (2d Cir. 2006). We analyze antitrust standing under a two-part test: a plaintiff must show (1) antitrust injury, which is "injury of the type the antitrust laws were intended to prevent and that flows from that which makes defendants' acts unlawful," *Brunswick Corp. v. Pueblo Bowl-O-Mat, Inc.*, 429 U.S. 477, 489, 97 S. Ct. 690, 50 L. Ed. 2d 701 (1977), and (2) that he is a proper plaintiff in light of four "efficient enforcer" factors:

> (1) the directness or indirectness of the asserted injury; (2) the existence of an identifiable class of persons whose self-interest would normally motivate them to vindicate the public interest in antitrust enforcement; (3) the speculativeness of the alleged injury; and (4) the difficulty of identifying damages and apportioning them among direct and indirect victims so as to avoid duplicative recoveries.

Volvo N. Am. Corp. v. Men's Int'l Prof'l Tennis Council, 857 F.2d 55, 66 (2d Cir. 1988) (citing *Associated Gen. Contractors v. Cal. State Council of Carpenters ("AGC")*, 459 U.S. 519, 540-45, 103 S. Ct. 897, 74 L. Ed. 2d 723 (1983)).

In this case, the plaintiffs are purchasers of the defendants' product who allege being forced to pay supra-competitive prices as a result of the defendants' anticompetitive conduct. Such an injury plainly is "of the type the antitrust laws were intended to prevent." *Brunswick*, 429 U.S. at 489; *see also AGC*, 459 U.S. at 530 ("Congress was primarily interested in creating an effective remedy for consumers who were forced to pay excessive prices by the giant trusts and combinations that dominated certain interstate markets."). Although the defendants' conduct at issue targeted their competitors, such as Barr, the plaintiffs' claimed injury of higher prices was "inextricably intertwined" with the conduct's anti-competitive effects and thus "flow[ed] from that which makes defendants' acts unlawful." *Blue Shield of Va. v. McCready*, 457 U.S. 465, 484, 102 S. Ct. 2540, 73 L. Ed. 2d 149 (1982) (internal quotation marks omitted). Antitrust injury is therefore present.

As for the "efficient enforcer" factors that bear on whether the plaintiffs are "proper" antitrust plaintiffs, spelled out in *Volvo*, each favors granting antitrust standing. With respect to the first factor, directness of injury, even though the plaintiffs' injuries were derivative of the direct harm experienced by the defendants' competitors, harming competitors was

simply a means for the defendants to charge the plaintiffs higher prices. *See id.* at 478-79; *In re Warfarin Sodium Antitrust Litig.*, 214 F.3d 395, 400-01 (3d Cir. 2000). This factor supports the plaintiffs' standing.

As to the second factor, motivation, the defendants argue that their competitors are the parties most motivated to enforce the antitrust laws, because the competitors were most directly impacted by the alleged anticompetitive behavior. They note that we declined to find antitrust standing in *Paycom* in part because the plaintiff there was "not an entity whose self-interest would most 'motivate [it] to vindicate the public interest in antitrust enforcement.'" 467 F.3d at 294 (quoting *AGC*, 459 U.S. at 542) (alteration in original). But this argument overlooks the fact that the *Paycom* court asked if the plaintiff was *an* entity most motivated by self-interest, not *the* entity most motivated by self-interest. *See id.* The second factor simply looks for a class of persons naturally motivated to enforce the antitrust laws. "Inferiority" to other potential plaintiffs can be relevant, but it is not dispositive. *See Andrx Pharms., Inc. v. Biovail Corp., Int'l*, 256 F.3d 799, 816, 347 U.S. App. D.C. 178 (D.C. Cir. 2001). Even if the competitors might be the most motivated, the plaintiffs are also significantly motivated due to their "natural economic self-interest" in paying the lowest price possible. *See Daniel v. Am. Bd. of Emergency Med.*, 42[illegible] F.3d 408, 444 (2d Cir. 2005) (internal quotation marks omitted).

Moreover, the defendants' competitors, unlike the plaintiffs, would be seeking lost profits, not overcharges. Lost profits are the difference between the competitive price and what the competitors' costs would have been, while overcharges are the difference between the defendants' supra-competitive price and the competitive price. Denying the plaintiffs a remedy in favor of a suit by competitors would thus be "likely to leave a significant antitrust violation undetected or unremedied." *AGC*, 459 U.S. at 542; *see also Andrx Pharms.*, 256 F.3d at 817 (noting that lost profits and overcharges are distinct injuries). The second factor supports standing.

Turning to speculativeness, the third factor, the defendants argue that the plaintiffs' allegations rest upon tenuous assumptions about the beneficial effects of generic competition. The assumptions are not as speculative as the defendants suggest. That no other manufacturer would have obtained a patent on the drug is a fair assumption, we think, given that "[t]he reluctance of the PTO to issue the '398 patent was evident" in advance of the defendants' inequitable conduct. *Ferring I*, 437 F.3d at 1186. And that generic manufacturers would have decided to compete for DDAVP sales is self-evident: manufacturers sought approval for generic DDAVP when the '398 patent was still enforceable. It may be difficult to account precisely for the likely effects of generic competition, but we have little doubt that those effects can be sufficiently estimated and measured here. *See Geneva Pharms. Tech. Corp. v. Barr Labs. Inc.*, 386 F.3d 485, 499 (2d Cir.

2004) (listing literature analyzing generic drug competition). This is especially so when "[t]he most elementary conceptions of justice and public policy require that the wrongdoer shall bear the risk of the uncertainty which his own wrong has created." *Bigelow v. RKO Radio Pictures*, 327 U.S. 251, 265, 66 S. Ct. 574, 90 L. Ed. 652 (1946). Like the first two factors, the third factor supports the plaintiffs' antitrust standing.

As for the fourth factor, the potential for duplicative recovery, the difference between lost profits and overcharges is again relevant. Even assuming some overlap between lost profits and overcharges (as could occur if generic manufacturers charged more than the competitive price), the two are conceptually different measures that we think can be fairly apportioned in order to avoid duplicative recoveries. *See Andrx Pharms.*, 256 F.3d at 817. This factor also supports the plaintiffs' antitrust standing.

In sum, then, although the relative weight given to each factor is imprecise, *see, e.g.*, *Daniel*, 428 F.3d at 443, the plaintiffs would be efficient enforcers under any formulation. What complicates the standing question, however, is the centrality of the alleged *Walker Process* fraud to the plaintiffs' case. *Walker Process* claims are based on a fraudulently obtained patent, and are typically brought as counterclaims in patent infringement suits: the plaintiff claims the defendant infringed his patent, and the defendant responds that the patent was invalid as fraudulently obtained, and that the plaintiff's enforcement efforts violate *Walker*

Process. See Nobelpharma AB v. Implant Innovations, Inc., 141 F.3d 1059, 1067 (Fed. Cir. 1998). If a patent is valid, a *Walker Process* claim cannot stand.

Outside of an infringement suit counterclaim, a patent's validity can be challenged only by a party (1) producing or preparing to produce the patented product, and (2) being threatened or reasonably likely to be threatened with an infringement suit. *See, e.g., Cordis Corp. v. Medtronic, Inc.*, 835 F.2d 859, 862 (Fed. Cir. 1987). As purchasers of DDAVP, the plaintiffs do not satisfy these requirements and cannot directly challenge the '398 patent's validity. As the district court noted, whether the plaintiffs have standing to bring their *Walker Process* claim, when a court has yet to find the '398 patent fraudulently obtained, is a question of first impression.

The defendants acknowledge that *Walker Process* standing might be warranted for a purchaser when a patent has already been held to have been fraudulently procured. But the defendants urge us to hold that, when dealing with a patent not yet found to be fraudulently obtained, a party has *Walker Process* standing only if that party also has standing to challenge the patent's validity. They argue that giving *Walker Process* standing to the plaintiffs, who cannot directly challenge the '398 patent's validity, could result in an avalanche of patent challenges, because direct purchasers otherwise unable to challenge a patent's validity could do so simply by dressing their patent challenge with a *Walker Process* claim. It would be relatively easy, the defendants argue,

for these purchasers to allege an antitrust injury, as patent protection inherently leads to supra-competitive prices. *See Zenith Radio Corp. v. Hazeltine Research, Inc.*, 395 U.S. 100, 135, 89 S. Ct. 1562, 23 L. Ed. 2d 129 (1969) ("A patentee has the exclusive right to manufacture, use, and sell his invention."). Given that *Walker Process* fraud converts this fundamental feature of the patent system into a potential antitrust violation, the defendants contend that finding purchaser standing could significantly increase the costs of defending and enforcing patents by greatly expanding the universe of potential challenges. They insist that "[i]f the threat of treble damage liability . . . were imbedded in the minds of potential patent holders as a likely prospect . . . , the efficacy of the economic incentives afforded by our patent system might be severely diminished." *SCM Corp. v. Xerox Corp.*, 645 F.2d 1195, 1206 (2d Cir. 1981).

Walker Process itself, of course, reflects a willingness to let antitrust liability impact the patent system. However, the defendants argue that *Walker Process* is the product of the Supreme Court's careful balancing of antitrust and patent policies, a balance which should not be upset and under which *Walker Process* plaintiffs must be independently able to first prove the patent's fraudulent procurement. Yet the language of *Walker Process* does not necessarily suggest such a limit:

> While one of [the claim's] elements is the fraudulent procurement of a patent, the action does not directly seek the patent's annulment. The gist of Walker's claim is that

> since Food Machinery obtained its patent by fraud it cannot enjoy the limited exception to the prohibitions of § 2 of the Sherman Act, but must answer under that section . . . to *those injured by any monopolistic action* taken under the fraudulent patent claim. Nor can the interest in protecting patentees from 'innumerable vexatious suits' be used to frustate the assertion of rights conferred by the antitrust laws.

382 U.S. at 176 (emphasis added). To be sure, the *Walker Process* Court also noted that allowing antitrust recovery "accord[ed]" with the "long-recognized procedures" that controlled how parties could challenge a patent's validity, 382 U.S. at 176-77, thereby suggesting that the Court may not have envisioned expanding the universe of potential patent challengers.

Nonetheless, we are reluctant to embrace the defendants' position because we are wary of creating the potential "to leave a significant antitrust violation undetected or unremedied." *AGC*, 459 U.S. at 542. As the defendants would have it, direct purchasers would be able to recover antitrust damages from a fraudulent patentee *only* after that patentee first loses on a fraudulent procurement claim. This asks too much of the generic competitors and other potential patent challengers, who may not have the strategic interest or the resources to start or win such a battle, or who may be presented with strong incentives to settle their challenge by patent holders seeking not only to

preserve their patent's enforceability, but also to avoid potential *Walker Process* liability. *See* C. Scott Hemphill, Paying for Delay: Pharmaceutical Patent Settlement as a Regulatory Design Problem, 81 N.Y.U. L. Rev. 1553, 1616 (2006) (noting how "an innovator has an especially strong incentive to pay to neutralize . . . potential competition" when a generic manufacturer first files an ANDA).

Although settlements between patent holders and generic manufacturers that delay generic entry into the market may themselves invite antitrust liability, a plaintiff must be able to show the settled litigation to have been a sham in order to succeed. *See Tamoxifen*, 466 F.3d at 208-09 ("In such a case, so long as the patent litigation is neither a sham nor otherwise baseless, the patent holder is seeking to arrive at a settlement in order to protect that to which it is presumably entitled: a lawful monopoly over the manufacture and distribution of the patented product."). A purchaser seeking to challenge the settlement by showing the underlying infringement litigation to be a sham would need to attach antitrust liability to the patent enforcement efforts — a move that would raise the same standing issues presented by this case. Thus, not only are there strong potential settlement incentives, but these settlements could be shielded from purchaser attack.

The difference between inequitable conduct and fraud also bears on the question. Inequitable conduct is a lesser showing than fraud, but is sufficient to render a patent unenforceable. A generic competitor interested

simply in selling its product may not value the higher showing of fraud enough to pursue it, especially if the competitor's antitrust damages would be minor or difficult to prove. Again, relying on generic competitors to lead the antitrust charge may ask too much of them.

On the other hand, we do not pass lightly over the defendants' objections to expanding the universe of patent challengers. The risk of disturbing the incentives for innovation dictates that we tread carefully. As a result, we decline to decide whether purchaser plaintiffs *per se* have standing to raise *Walker Process* claims. In this case, the plaintiffs are challenging an already tarnished patent. We are able to grant them antitrust standing without altering the typical limits on who can start a challenge to a patent's validity. We therefore hold only that purchaser plaintiffs have standing to raise *Walker Process* claims for patents that are already unenforceable due to inequitable conduct. The district court erred by concluding to the contrary.

III. Was the Antitrust Claim Adequately Pled

Granting standing to the plaintiffs does not resolve this appeal, because the district court also concluded that the plaintiffs had failed to state a claim. "We review the district court's dismissal of a complaint for failure to state a claim *de novo*, accepting as true all facts alleged in the complaint and drawing all inferences in favor of the plaintiff . . . ." *Faulkner v. Beer*, 463 F.3d 130, 133 (2d Cir. 2006) (internal quotation marks omitted). "[O]nly a complaint that states a plausible claim

for relief survives a motion to dismiss." *Ashcroft v. Iqbal*, 129 S. Ct. 1937, 1950, 173 L. Ed. 2d 868 (2009). We believe that the plaintiffs meet this standard for their antitrust claim under each of their four theories.

Walker Process fraud, the plaintiffs' first theory, requires:

> (1) a representation of a material fact, (2) the falsity of that representation, (3) the intent to deceive or, at least, a state of mind so reckless as to the consequences that it is held to be the equivalent of intent (scienter), (4) a justifiable reliance upon the misrepresentation by the party deceived which induces him to act thereon, and (5) injury to the party deceived as a result of his reliance on the misrepresentation.

Nobelpharma, 141 F.3d at 1069-70. A fraudulent omission, which "can be just as reprehensible as a fraudulent misrepresentation," can be sufficient to "support a finding of *Walker Process* fraud." *Id.* at 1070.

A party "alleging fraud or mistake . . . must state with particularity the circumstances constituting fraud or mistake." Fed. R. Civ. P. 9(b). The plaintiffs argue that they have pled each element with sufficient specificity. They alleged a series of "highly material" omissions, without which "the '398 patent would not have issued." Compl. ¶ 74. The Federal Circuit agreed on the "high[ ] material[ity]" of the omissions when it found the '398

patent unenforceable. *Ferring I*, 437 F.3d at 1194. The *Ferring I* litigation also addressed the third element of intent, as the district court found "clear and convincing evidence of an intent to mislead the examiners." *Ferring B.V.*, 2005 U.S. Dist. LEXIS 3597, 2005 WL 437981, at *9. Reliance and injury, the fourth and fifth elements, are straightforward here: the PTO was justified in relying on the information the defendants provided, and injury is a "matter of course whenever the other four elements are met." *Unitherm Food Sys., Inc. v. Swift-Eckrich, Inc.*, 375 F.3d 1341, 1361 (Fed. Cir. 2004), *rev'd on other grounds*, 546 U.S. 394, 126 S. Ct. 980, 163 L. Ed. 2d 974 (2006). Thus, the plaintiffs contend the district court's dismissal on the pleadings was erroneous.

The defendants respond that the district judge's rejection of the plaintiffs' claim must be affirmed because he was also the district judge in the initial infringement litigation, in which he held the '398 patent unenforceable. The defendants argue that the judge's involvement in both cases enabled him to validly conclude that his previous findings could not support a claim of fraudulent procurement in the instant case. This is a logical non sequitur. The district judge could be correct in determining that inequitable conduct occurred and yet mistaken that such conduct did not amount to fraud. Moreover, the defendants' argument ignores the distinction between findings and pleadings. Even if the district judge was correct that the earlier record did not show fraud, the record in this case could be different following discovery.

The defendants contend that simply adding a conclusory allegation of fraud to the previous findings is inadequate to meet the plaintiffs' obligation to "allege facts that give rise to a strong inference of fraudulent intent." *Acito v. IMCERA Group, Inc.*, 47 F.3d 47, 52 (2d Cir. 1995). We are, however, "lenient in allowing scienter issues to withstand summary judgment based on fairly tenuous inferences," because such issues are "appropriate for resolution by the trier of fact." *Press v. Chem. Inv. Servs. Corp.*, 166 F.3d 529, 538 (2d Cir. 1999). The same holds true for allowing such issues to survive motions to dismiss. The district court found "an intent to deceive" in the patent litigation. *Ferring B.V.*, 2005 U.S. Dist. LEXIS 3597, 2005 WL 437981, at *9. Granting the plaintiffs all favorable inferences as we must on a motion to dismiss, and given that the omissions at issue occurred repeatedly over a period of years, this intent is sufficient to plausibly support a finding of *Walker Process* fraud.

The defendants next argue that the plaintiffs must allege evidence of intent distinct from the omission itself. While a false or clearly misleading statement can permit an inference of deceptive intent, a misrepresentation in the form of an omission is more likely to be innocent and cannot support *Walker Process* fraud without "evidence of intent separable from the simple fact of the omission." *Dippin' Dots, Inc. v. Mosey*, 476 F.3d 1337, 1347 (Fed. Cir. 2007). The issue in the initial infringement litigation was inequitable conduct, not *Walker Process* fraud. Moreover, the district court in that litigation correctly noted that high materiality could

overcome a lesser showing of intent. *Ferring B.V.*, 2005 U.S. Dist. LEXIS 3597, 2005 WL 437981, at *9; *see Brasseler, U.S.A. I., L.P. v. Stryker Sales Corp.*., 267 F.3d 1370, 1380-81 (Fed. Cir. 2001). While such balancing is impermissible with *Walker Process* claims, we think the plaintiffs' allegations are nonetheless sufficient. *Dippin' Dots* concerned findings, not pleadings, *see* 476 F.3d at 1341-42; even if the district court's findings in the *Ferring I* litigation could not satisfy *Dippin' Dots*, the plaintiffs' pleadings could plausibly lead to additional findings that would satisfy *Dippin' Dots*, which is all that is required at this stage of the litigation.

The defendants additionally argue that the allegations of materiality are insufficient. Specifically, they contend that the plaintiffs do not dispute the '398 patent's patentability on the merits or claim that, but for the alleged fraud, no patent could have been issued to anyone. For antitrust purposes, whether a patent could be issued matters more than who would possess it; if a patent could still "have been issued to someone," its market power would still have been concentrated (properly) in one party. *Brunswick Corp. v. Riegel Textile Corp.*, 752 F.2d 261, 265 (7th Cir. 1984). As a result, *Walker Process* fraud must concern a material issue of patentability; otherwise, a patent would have issued regardless of any fraud, and potential plaintiffs would have suffered the same monopoly effects (but legitimately).

Although the plaintiffs do not address patentability directly in the complaint, the issue is implicit in their

allegations. The defendants' allegedly fraudulent affidavits were attempts to explain away prior art. The Federal Circuit found them "absolutely critical" to the defendants' overcoming the patent application's initial rejection. *Ferring I*, 437 F.3d at 1189. Whether or not these declarations, if accompanied by full disclosure, would have resulted in an enforceable patent is debatable, but we think that, at the pleading stage, the fact of non-disclosure is sufficient to properly allege materiality. Overall, then, the plaintiffs have sufficiently alleged *Walker Process* fraud to survive the defendants' motion to dismiss on the pleadings.

We likewise conclude that the sham litigation claim has been adequately alleged. In order to state a claim for sham litigation, the plaintiffs need to allege that "the litigation in question is: (i) 'objectively baseless,' and (ii) 'an attempt to interfere directly with the business relationships of a competitor through the use of the governmental process . . . as an anticompetitive weapon.'" *Primetime 24 Joint Venture v. Nat'l Broadcasting Co.*, 219 F.3d 92, 100-01 (2d Cir. 2000) (citing *Prof'l Real Estate Investors, Inc. v. Columbia Pictures Indus., Inc.*, 508 U.S. 49, 60, 113 S. Ct. 1920, 123 L. Ed. 2d 611 (1993)). Based on the same facts alleged to sustain a *Walker Process* claim, we find that in the circumstances of this case, the plaintiffs' allegations are also sufficient to make out a sham litigation claim. The defendants effectively concede as much. *See* Brief of Defendants-Appellees Ferring B.V. and Ferring Pharms. at 38 ("[A] sham litigation claim here not only requires proof that defendants defrauded

the PTO, but also that they knew their misconduct before the PTO had rendered the patent invalid. . . . [Plaintiffs'] 'sham' litigation allegation is thus substantively duplicative of their patent fraud claim. . . .").

The plaintiffs also may proceed on their Orange Book claim. The defendants all but concede that the plaintiffs would have a basis for contending the Orange Book listing was fraudulent if the '398 patent is found to have been fraudulently procured. *See id.* at 41 ("[T]he allegations regarding the Orange Book listing are — like the sham litigation claims — purely derivative of the underlying claim that the '398 patent was fraudulently procured."). Indeed, the Orange Book listing's validity flows from the patent's validity. Having determined that the *Walker Process* and sham litigation theories are still in play, we similarly conclude that the plaintiffs have adequately alleged that the defendants improperly listed the '398 patent in the FDA's Orange Book.

The final theory is the plaintiffs' citizen petition theory, which, as we have explained, stands apart from the '398 patent's validity. The district court dismissed this theory on the basis that it concerned petitioning activity protected by the First Amendment. *Id.* To reach this conclusion, the district court presumably reasoned that the plaintiffs could not plausibly show the petition to be a sham, i.e., objectively and subjectively baseless, a proposition with which we disagree. The FDA found that the citizen petition "had no convincing evidence"

and lacked "any basis" for its arguments. Compl. ¶ 115 (internal quotation marks and emphasis omitted). In the *Ferring I* litigation, the district court suggested that the petition might have been "nothing more than a hardball litigation tactic, motivated by a desire to keep out competition for as long as possible after the expiration of the patent and raise transactional costs for Barr." *Ferring B.V.*, 2005 U.S. Dist. LEXIS 3597, 2005 WL 437981, at *17. Together, these findings indicate the plaintiffs could plausibly show the citizen petition to have been a sham.

Finally, the defendants contend that the citizen petition cannot give rise to antitrust liability because it could not have impacted the FDA's decision, as the FDA ultimately rejected the petition. But this ignores the possibility that the sham petition caused a delay in generic competition, a possibility reinforced by the fact that the FDA approved the generic drug on the same day that it rejected the petition. *See* 21 C.F.R. § 10.35(d)(1) (enabling a stay of FDA action after the filing of a petition). Whether the '398 patent was valid on the date the petition was filed is immaterial to this theory's success, because the plaintiffs can plausibly show the patent to have been fraudulently procured. It may turn out at trial that this petition was not a sham, or that the FDA's approval of the generic drug was not delayed by the petition, but the possibility that the petition was a sham, and that it impacted the FDA's decision, is sufficiently plausible to defeat the motion to dismiss.

Overall, the plaintiffs have stated an antitrust claim upon which relief may be granted. Based on the pleadings, each of their four theories could plausibly succeed. The district court erred by concluding to the contrary.

IV. Can Aventis Be Kept in the Case

The district court also granted Aventis's separate motion to dismiss, concluding that the plaintiffs had not alleged fraud with sufficient particularity to satisfy Rule 9 of the Federal Rules of Civil Procedure. "Although Rule 9(b) permits knowledge to be averred generally, plaintiffs must still plead the events which they claim give rise to an inference of knowledge." *Devaney v. Chester*, 813 F.2d 566, 568 (2d Cir. 1987). In a case involving multiple defendants, plaintiffs must plead circumstances providing a factual basis for scienter for each defendant; guilt by association is impermissible. *See id.* This can consist of allegations as to who "possessed . . . knowledge" of the fraud, "when and how they obtained [that] knowledge," or even why they "should have known" of the fraud. *Id.* The district court concluded that the plaintiffs fell short of this standard. We disagree.

In the district court's view, "[t]hat Aventis would pay to license a patent which it knew to be unenforceable flies in the face of reason." *In re DDAVP*, 2006 U.S. Dist. LEXIS 96201, *25. However, we find the plaintiffs' allegations plausible, and sufficient to survive a motion to dismiss on the pleadings. At the time Aventis filed

its NDA and listed DDAVP in the Orange Book, the '398 patent's validity was already in question with the patent having been rejected twice, and the PTO having raised concerns of bias. *See Ferring I*, 437 F.3d at 1190. Yet, the plaintiffs assert that Aventis apparently made no effort to independently investigate and attest to the validity of the '398 patent. Rule 9(b) requires only the *circumstances* of fraud to be stated with particularity; knowledge itself can be alleged generally. Especially considering the long-standing relationship between Aventis and Ferring, the plaintiffs have adequately stated circumstances that give rise to a plausible inference of knowledge and liability. At this early stage, the plaintiffs need only state a plausible claim of monopolization, and they have alleged enough for their suit against Aventis to proceed.

Because the dismissal as to both Ferring and Aventis was in error, we have no cause to address the plaintiffs' claim that their due process rights were violated.

CONCLUSION

For the foregoing reasons, we VACATE the district court's dismissal of the plaintiffs' case and REMAND for further proceedings.

APPENDIX B — MEMORANDUM AND ORDER OF THE UNITED STATES DISTRICT COURT FOR THE SOUTHERN DISTRICT OF NEW YORK DATED NOVEMBER 2, 2006

UNITED STATES DISTRICT COURT FOR THE SOUTHERN DISTRICT OF NEW YORK

05 Cv. 2237 (CLB)

IN RE: DDAVP DIRECT PURCHASER ANTITRUST LITIGATION;

IN RE: DDAVP INDIRECT PURCHASE ANTITRUST LITIGATION;

THIS DOCUMENT RELATES TO: ALL ACTIONS

Memorandum and Order

Brieant, J.

Before the Court in this consolidated anti-trust class action litigation, are two motions to dismiss the Direct and Indirect Purchasers' separate class action Complaints. By joint motion filed May 1, 2006 (Doc. No. 32), Defendants Ferring B.V. and Ferring Pharmaceuticals ("Ferring") and Aventis Pharmaceuticals move to dismiss the Complaints for failure to state a claim. By motion also filed May 1, 2006 (Doc. No. 35), Defendant Aventis separately moves for the same relief. Opposition papers were filed separately by the Direct and Indirect Purchasers on June 16, 2006 and reply papers were filed July 17, 2006. Oral argument

on the motions was heard on July 21, 2006. No motion for class certification has been filed.

This case is presented as a nationwide class action, alleging violations of federal and state antitrust law, as well as unfair and deceptive trade practices. The Direct and Indirect Purchaser Plaintiffs filed their respective class action Complaints against Defendants after this Court held that a patent held by Ferring for desmopressin acetate ("DDAVP") tablets was unenforceable due to inequitable conduct before the United States Patent and Trademark Office ("PTO").[1]

The following facts are either undisputed or presumed true for purposes of these motions only. Plaintiffs' claims arise from the manufacture and marketing of DDAVP, an antidiuretic, and its generic equivalents, called desmopressin acetate. Ferring is a privately held company under the laws of the Netherlands, which developed the drug and manufactured it. Ferring is the owner and assignee of U.S. Patent No. 5,407,398 entitled "DDAVP Antidiuretic

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1. The Federal Circuit affirmed. *See Ferring B.V. v. Barr Labs., Inc.*, 437 F.3d 1181, 1192 (Fed. Cir. 2006) *("Ferring I")*. A motion for rehearing or rehearing *en banc* was denied. *See Ferring B.V. v. Barr Labs., Inc.*, 2006 U.S. App. LEXIS 10765 (Fed. Cir. 2006); *see also Ferring B.V. v. Barr Labs., Inc.*, 2006 U.S. App. LEXIS 10811 (Fed. Cir. 2006). A Petition for a Writ of Certiorari was filed with the Supreme Court on September 11, 2006, an extension having been granted by Chief Justice Roberts, and certiorari was denied by the United States Supreme Court on October 30, 2006.

and Method Therefor" ("'398 patent"). The '398 patent issued on September 10, 1991. Aventis is a Delaware Corporation licensed to market and sell the invention of the '398 patent in the United States. Aventis is also the holder of an approved new drug application ("NDA"), No. 019-955, for desmopressin acetate tablets which are marketed in the United States under the product name DDAVP[R].

Plaintiffs allege that Defendants Ferring and Aventis unlawfully maintained a monopoly in the relevant market by: 1) procuring the '398 patent through fraud and/or inequitable conduct before the PTO; 2) by improperly listing the patent in the United States Food and Drug Administration's ("FDA") publication of approved "Reference Listed Drugs" called the *Orange Book*, so as to be able to assert patent infringement claims against potential competitors; 3) by instituting and prosecuting a "sham" patent infringement litigation against Barr and Teva in order to delay FDA approval of and market entry of generic DDAVP tablets; and 4) by filing a "sham" citizen petition with the FDA in an effort to further delay final FDA approval of generic desmopressin acetate tablets.

Plaintiffs allege that Defendants unreasonably restrained, suppressed and eliminated competition in the market for DDAVP and its generic equivalents, by illegally obtaining and maintaining a monopoly. The Complaints are substantially similar, but the Indirect Purchaser Plaintiffs also make claims and seek damages under the antitrust and consumer protection statutes of 23 different states. All Plaintiffs allege that as a result of Defendants' conduct, Plaintiffs and proposed Class

Members paid up to hundreds of millions of dollars more for DDAVP at "supra-competitive" prices, than they would have if competing and/or generic versions of the drug had been available. Plaintiffs allege that Defendants' purpose in proceeding with earlier patent infringement litigation (in this Court) was in order to invoke the thirty-month Hatch-Waxman stay, despite knowledge that the '398 patent had been procured by fraud and was unenforceable.

As just noted, the Indirect Purchasers' Complaint includes state claims brought under the antitrust and consumer protection statutes of the Indirect Purchaser States based on illegal monopolization of the DDAVP market. Indirect Purchasers seek disgorgement of Defendants' profits from sales of DDAVP to the extent that Defendants have been unjustly enriched.

The Direct Purchaser Plaintiffs propose the following class:

> All persons and entities in the United States that purchased DDAVP in tablet form directly from one or more of the Defendants at any time from February 18, 2001 through the date on which the anti-competitive effects of Defendants' conduct cease (the "Class Period"). Excluded from the Class are Defendants, their parents, subsidiaries and affiliates, employees, and federal government entities.

Direct Purchasers' Consolidated Amended Class Action Complaint ("Direct Purchaser Complaint") at ¶15.

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The Indirect Purchasers or Third-Party Plaintiffs propose the following class:

> All persons or entities throughout the United States and its territories who purchased and/or paid for DDAVP or generic versions of DDAVP for consumption by themselves, their families, or their members, employees, insureds, participants or beneficiaries (the "Class") during the period from February 25, 2001, through the date on which the anticompetitive effects of Defendants' conduct cease ("the Class Period"). For purposes of the Class definition, persons and entities "purchased" DDAVP if they paid some or all of the purchase price.

Indirect Purchasers' Consolidated Class Action Complaint ("Indirect Purchaser Complaint") at ¶124.

Defendants Ferring and Aventis jointly move to dismiss on the bases that: 1) Plaintiffs lack standing to assert the anti-trust violations claimed; 2) that Indirect Purchaser Plaintiffs' state-law claims are preempted by federal patent law; and 3) that the state law claims suffer from other defects, meriting dismissal. Defendant Aventis also moves separately to dismiss the Complaints on the basis that Plaintiffs have not sufficiently alleged misconduct by Aventis in relation to the antitrust allegations.

Defendants' Joint Motion to Dismiss the Complaint for Failure to State a Claim

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Generally, patents can be enforced without violating the Sherman Act and patents are intended in part to keep competition off of the market for a designated period of time. Enforcing a patent to stifle competition could only be actionable if there were a wilful and knowing use of an invalid patent, which violated antitrust laws. Defendants argue that this antitrust suit is an indirect and impermissible attempt to collaterally attack the validity of the patent, while Plaintiffs respond that it is rather a garden variety antitrust claim of monopolization.

Defendants argue that Plaintiffs lack standing to assert the federal and state law claims because they are purchasers and not competitors or would-be competitors of Ferring, and because neither Ferring nor Aventis has ever threatened to enforce the patents against Plaintiff purchasers. They argue that the Court should find that the purchaser-Plaintiffs have no standing, and that "it is entirely reasonable to limit antitrust standing, . . . to only those entities directly threatened with the enforcement of a patent." *Reply at 2.*[2]

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2. The Court notes the unusual circumstance in this case, that none of the generic manufacturers, originally sued by Ferring for infringement of the '398 patent, asserted antitrust counterclaims. *See April 15, 2005 Transcript at 41-42.* "An antitrust claim premised on stripping a patentee of its immunity under the antitrust laws, is typically raised as a counterclaim by a defendant in a patent infringement. suit." *Nobelpharma Ab v. Implant Innovations*, 141 F.3d 1059, 1067 (Fed. Cir. 1998).

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It is well established that conduct in obtaining and enforcing a patent is immune from antitrust allegations, as a form of petitioning protected by the First Amendment. In *Walker Process*, the Supreme Court addressed the issue of "whether the maintenance and enforcement of a patent obtained by fraud on the Patent Office may be the basis of an action under §2 of the Sherman Act, and therefore subject to a treble damage claim by an injured party under §4 of the Clayton Act," and held that the enforcement of a patent procured by fraud on the Patent Office may be violative of §2 of the Sherman Act, provided the other elements necessary to a §2 case are present. *See Walker Process Equip., Inc., v. Food Mach. & Chem Corp.*, 382 U.S. 172, 173, 86 S. Ct. 347, 15 L. Ed. 2d 247 (1965).

The Court of Appeals for the Federal Circuit has held:

> A patentee who brings an infringement suit may be subject to antitrust liability for the anti-competitive effects of that suit if the alleged infringer (the antitrust plaintiff) proves (1) that the asserted patent was obtained through knowing and willful fraud within the meaning of *Walker Process*, or (2) that the infringement suit was "a mere sham to cover what is actually nothing more than an attempt to interfere directly with the business relationships of a competitor," *Eastern R.R. Presidents Conference v. Noerr Motor Freight, Inc.*, 365 U.S. 127, 81 S. Ct.

> 523, 5 L. Ed. 2d 464 (1961); *California Motor Transp. Co. v. Trucking Unlimited*, 404 U.S. 508, 510, 92 S. Ct. 609, 30 L. Ed. 2d 642 (1972) (holding that *Noerr* "governs the approach of citizens or groups of them . . . to courts, the third branch of Government"). *See Professional Real Estate Investors, Inc. v. Columbia Pictures Indus., Inc.*, 508 U.S. 49, 62 n.6, 113 S. Ct. 1920, 123 L. Ed. 2d 611, (1993) (PRE) (declining to decide "whether and, if so, to what extent *Noerr* permits the imposition of antitrust liability for a litigant's fraud or other misrepresentations").

Nobelpharma, 141 F.3d at 1068 (some citations omitted). That Court has also set forth the following with regard to fraud:

> Applied to patent prosecution, fraud requires (1) a false representation or deliberate omission of a fact material to patentability, (2) made with the intent to deceive the patent examiner, (3) on which the examiner justifiably relied in granting the patent, and (4) but for which misrepresentation or deliberate omission the patent would not have been granted. A finding of fraud can of itself render the patent unenforceable, and when accompanied by the elements of violation of the Sherman Act, as discussed in Part VI, can incur additional consequences.

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C.R. Bard, Inc. v. M3 Sys., Inc., 157 F.3d 1340, 1364 (Fed. Cir. 1998). In *Nobelpharma*, the Court explained:

> In *Walker Process*, the Supreme Court held that in order "to strip [a patentee] of its exemption from the antitrust laws" because of its attempting to enforce its patent monopoly, an antitrust plaintiff is first required to prove that the patentee "obtained the patent by knowingly and willfully misrepresenting facts [ ] to the [PTO]." 382 U.S. at 177. The plaintiff in the patent infringement suit must also have been aware of the fraud when bringing suit.

Nobelpharma, 141 F.3d at 1068-1069.

As held in *Walker Process*, "[i]t must be remembered that we deal only with a special class of patents, i.e., those procured by intentional fraud." *Walker Process*, 382 U.S. at 172. A finding of *Walker Process* fraud "must be based on independent and clear evidence of deceptive intent together with a clear showing of reliance, i.e., that the patent would not have issued but for the misrepresentation or omission." *Nobelpharma*, 141 F.3d at 1071.

The '398 patent now stands as unenforceable for inequitable conduct, but that misconduct has not been

shown to rise to the level of fraud, so as to lead to invalidity.

> Inequitable conduct is thus an equitable defense in a patent infringement action and serves as a shield, while a more serious finding of fraud potentially exposes a patentee to antitrust liability and thus serves as a sword. . . . [T]he remedies for inequitable conduct, while serious enough, only include unenforceability of the affected patent or patents and possible attorney fees. See 35 U.S.C. §§ 282, 285 (1994). Simply put, Walker Process fraud is a more serious offense than inequitable conduct.

Id. at 1070.

Fraud "must evidence a clear intent to deceive the examiner and thereby cause the PTO to grant an invalid patent." *Id at 1071.* In contrast, "a conclusion of inequitable conduct may be based on evidence of a lesser misrepresentation or an omission, such as omission of a reference that would merely have been considered important to the patentability of a claim by a reasonable examiner." *Id.* Fraud requires a higher threshold of both intent and materiality than does a finding of inequitable conduct and must be based on independent and clear evidence of deceptive intent together with a clear showing of reliance. *Id. at 1070-1071.*

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The Court's findings in the prior litigation of inequitable conduct and unenforceability do not arise to the *Walker Process* requirements of fraud and invalidity. At the very least, an additional component of scienter must be shown to render actions fraudulent that might otherwise be found merely inequitable. This Court did not determine that fraud was perpetrated on the PTO, nor that but for the omissions found, the patent would not have issued. Nor could it have done so on the complete record presented in *Ferring I*.[3]

Fraud must be pleaded with particularly, under Rule 9(b) of the Federal Rules of Civil Procedure ("FRCP"). Plaintiffs did not do so, and cannot do so, consistently with the record in *Ferring I*. For this reason alone, granting the motions to dismiss is appropriate.

The Court now considers in the interest of completeness whether these plaintiffs are "proper" antitrust plaintiffs, having standing to state a *Walker Process* claim.

> The offense of monopoly under § 2 of the Sherman Act has two elements: (1) the possession of monopoly power in the relevant market and (2) the willful acquisition or maintenance of that power as distinguished from growth or development as a consequence

3. In her dissent in *Ferring I*, Judge Newman noted that the record "does not indicate sufficient culpability to require a finding of intent to deceive." *Id* at p. 1205.

> of a superior product, business acumen, or historic accident.

United States v. Grinnell Corp., 384 U.S. 563, 570-571, 86 S. Ct. 1698, 16 L. Ed. 2d 778 (U.S. 1966).

Our Court of Appeals has held:

> To state a claim under the Sherman Act, a plaintiff, in addition to stating an antitrust violation, must allege facts sufficient to prove that it suffered antitrust injury, which is to say injury of the type the antitrust laws were intended to prevent and that flows from that which makes defendants' acts unlawful. The injury should reflect the anticompetitive effect either of the violation or of anticompetitive acts made possible by the violation. Harm to the antitrust plaintiff is sufficient to satisfy the constitutional standing requirement of injury in fact.

Joblove v. Barr Labs., Inc. (In re Tamoxifen Citrate Antitrust Litig.), 466 F.3d 187, 219, 2006 U.S. App. LEXIS 22154, *93 (2d Cir. 2006)(citations and quotations omitted).

The harm alleged by Plaintiffs in this case is in a monopoly, which kept generic versions of DDAVP off of the market and resulted in overcharges to Plaintiffs. Plaintiffs have not alleged and cannot, that they did compete or would have competed with Defendants, nor

that have they been sued or threatened with an infringement lawsuit by Defendants. Rather, they allege that they have paid higher prices for desmopressin acetate by virtue of Defendant's misconduct before the PTO and subsequent actions, which prevented the lower prices, which would have ensued from generic competition.

In *Associated General,* the Supreme Court discussed the standards for establishing standing to bring a Section 2 Sherman Act claim under Section 4 of the Clayton Act. In regard to "antitrust standing," it stated:

> The label "antitrust standing" has traditionally been applied to some of the elements of this inquiry. As commentators have observed, the focus of the doctrine of "antitrust standing" is somewhat different from that of standing as a constitutional doctrine. Harm to the antitrust plaintiff is sufficient to satisfy the constitutional standing requirement of injury in fact, but the court must make a further determination whether the plaintiff is a proper party to bring a private antitrust action.

Associated General Contractors v. Cal. State Council of Carpenters, 459 U.S. 519, 535 n.31, 103 S. Ct. 897, 74

L. Ed. 2d 723 (U.S. 1983)(citations omitted). In a subsequent case, the Supreme Court noted:

> A showing of antitrust injury is necessary, but not always sufficient, to establish standing under § 4, because a party may have suffered antitrust injury but may not be a proper plaintiff under § 4 for other reasons. Thus, in *Associated General Contractors* we considered other factors in addition to antitrust injury to determine whether the petitioner was a proper plaintiff under § 4.

Cargill, Inc. v. Monfort of Colorado, Inc., 479 U.S. 104, 110, 107 S. Ct. 484, 93 L. Ed. 2d 427 (U.S. 1986)(citations omitted). Our Court of Appeals summarized the factors of *Associated General as:*

> (1) the causal connection between the alleged antitrust violation and the harm to the plaintiff; (2) the existence of an improper motive; (3) whether the injury was of a type that Congress sought to redress with the antitrust laws; (4) the directness of the connection between the injury and alleged restraint in the relevant market; (5) the speculative nature of the damages; and (6) the risk of duplicative recoveries or complex apportionment of damages.

Balaklaw v. Lovell, 14 F.3d 793, 798 (2d Cir. 1994). The Court explained:

> Over time, courts have developed a two-pronged analysis to determine whether a

> plaintiff has antitrust standing. As a necessary first step, courts must determine whether the plaintiff suffered an antitrust injury. If the answer to that question is yes, they must then determine whether any of the other factors, largely relating to the directness and identifiability of the plaintiff's injury, prevent the plaintiff from being an efficient enforcer of the antitrust laws.

Id.

Although several district courts have addressed the question, there is no precedent binding upon this Court with regard to the specific issue of whether purchaser plaintiffs like those in this case have standing to assert a *Walker Process* claim. Plaintiffs rely on the holding of *Walgreen Co. v. Organon, Inc. (In re Remeron Antitrust Litig.) ("Remeron")*, 335 F. Supp. 2d 522 (D.N.J. 2004) (Hochbert, J.), in which the United States District Court for the District of New Jersey was faced with a case similar to the case at bar. Direct purchasers of a drug sued the manufacturer under the Sherman and Clayton Acts, claiming that fraud was perpetrated on the PTO by the manufacturer, which then monopolized the market for that drug. The *Remeron* Court concluded that a plaintiff does not have standing to state a *Walker Process* claim unless the defendant had sought to

enforce the patent against that plaintiff, or if the plaintiff had a reasonable basis for fearing such an attempted enforcement. *See Id.* at 529. The Court reasoned:

> Plaintiffs, as direct purchasers, neither produced mirtazapine nor would have done so; moreover, Plaintiffs were not party to the initial patent infringement suits. Plaintiffs may not now claim standing to bring a *Walker Process* claim by donning the cloak of a Clayton Act monopolization claim.

Id.

To the same effect, *see In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 363 F. Supp. 2d 514 (E.D.N.Y. 2005)(Trager, J.) *("Cipro")*, in which drug manufacturers' agreements settling patent infringement litigation were alleged to prevent competition for an antibiotic in violation of antitrust laws. It was held that non-infringing consumers of patented products have no cause of action to invalidate a patent, and *Walker Process* claims were preempted because they arise out of, and rest on patent law. *See Contra: Molecular Diagnostics Labs. v. Hoffmann-La Roche, Inc.*, 402 F. Supp. 2d 276, 280 (D.D.C. 2005) (Kennedy, J.), holding that customer plaintiffs have standing to litigate a *Walker Process* claim.

This Court concludes that the Courts in *Ciproflaxen* and *Remeron* have the better side of the argument.

Appendix B

Plaintiffs in *Walker Process* were competitors, and not purchasers. *See Indium Corp. of America v. Semi-Alloys, Inc.*, 566 F. Supp. 1344 (N.D.N.Y. 1983) *(Walker Process* claim dismissed for failure to adequately allege any set of facts that would amount to enforcement, attempted enforcement, or threatened enforcement of defendant's patents vis-a-vis the plaintiff). As herein earlier noted and as noted by Judge McCurn in *Indium Corp.*, the Supreme Court stated explicitly in *Walker Process:* "We have concluded that the *enforcement* of a patent procured by fraud on the Patent Office may be violative of § 2 of the Sherman Act provided the other elements necessary to a § 2 case are present." *Indium Corp.*, 566 F.Supp. at 1353 (emphasis added), *citing Walker Process.*, 382 U.S. at 174.

In this case, there has been no enforcement of the patent against the customer Plaintiffs. For want of antitrust standing, as an alternative ground, the motions shall be granted.

Plaintiffs' Sham Litigation Claims

Plaintiffs argue, and Defendants deny that even if the Court should find that they lack standing to pursue *Walker Process* claims, they may nonetheless pursue a "sham litigation" claim. Plaintiffs argue that Defendants conducted sham litigation by the filing of the original infringement action against Barr Laboratories, *(Ferring I)* by listing the patent in the Orange Book of patents, and by the filing of a citizen's petition, asking that the FDA require Barr to submit additional tests of

bio-equivalence, which Plaintiffs argue was done for delay.

"Under *Professional Real Estate Investors v. Columbia Pictures Indus.*, 508 U.S. 49, 113 S. Ct. 1920, 123 L. Ed. 2d 611 (1993)], a sham suit must be both subjectively brought in bad faith and based on a theory of either infringement or validity that is objectively baseless. Accordingly, if a suit is not objectively baseless, an antitrust defendant's subjective motivation is immaterial." *Nobelpharma*, 141 F.3d at 1072. "In contrast with a *Walker Process* claim, a patentee's activities in procuring the patent are not necessarily at issue." *Id.*

Clearly Aventis had the right to bring suit, since it was not privy to the inequitable conduct. The bringing of the suit by Ferring and Aventis was not in subjective bad faith, but rather a standard response to Hatch-Waxman. Every losing litigant in the federal courts does not become a sham litigant merely by losing their case.

The same is true of the citizen petition, which is First Amendment protected activity even though delay of Barr's access to the market was foreseeable.

These claims are also dismissed.

Appendix B

Aventis' Motion to Dismiss the Complaints

Aventis also moves separately (Doc. No. 35) to dismiss the Complaints, arguing that Plaintiffs have not adequately alleged any knowing participation by Aventis in the alleged fraud on the PTO and other activities. Rule 9 of the FRCP requires that: "[i]n all averments of fraud or mistake, the circumstances constituting fraud or mistake shall be stated with particularity. Malice, intent, knowledge, and other condition of mind of a person may be averred generally." *FRCP Rule 9(b).* On a motion to dismiss for failure to plead fraud with sufficient particularity, Plaintiffs are bound by the standards of Rule 9(b), but are entitled to reasonable inferences from the facts alleged.

As earlier mentioned, Aventis is the exclusive licensee of the patent for the sale of DDAVP tablets in the United States. Plaintiffs alleged that for over thirty years, Aventis has had a "close working relationship with Ferring," and note Ferring's description of its "key commercial partnership" with Aventis. *Direct Purchaser Complaint at* ¶ 42. They argue that in the process of applying for a New Drug Application from the FDA (held by Aventis, and not Ferring), between 1989 and 1991, Aventis had to make a certification of whether there was a patent that claims the product, or a patent on which a reasonable patent infringement suit could be brought. Plaintiffs contend that between 1989 and 1991, while Ferring was submitting declarations with omissions, that Aventis had to be aware of those declarations and that Aventis had to have knowledge

of the status of the patent because the NDA would had to have been amended once the patent was granted. No such *res ipsa* is apparent to this Court. Plaintiffs also contend that Aventis had performed its own study, and therefore "must have known" that the Citizen's Petition filed by Ferring requesting the FDA to require further bioequivalence testing was baseless. This does not, in logic follow, nor is there reason to believe that having made internal studies of its own, a citizen is blocked from petitioning for studies by the FDA.

> To survive a motion to dismiss, a plaintiff bringing suit under section 1 of the Sherman Act need not allege facts that exclude the possibility that the behavior of which complaint is made is legal. *See Twombly*, 425 F.3d at 111 ("[S]hort of the extremes of 'bare bones' and 'implausibility,' a complaint in an antitrust case need only contain the 'short and plain statement of the claim showing that the pleader is entitled to relief that Rule 8(a) requires."). However, bald assertions and conclusions of law are not adequate [to state a claim] and a complaint consisting only of naked assertions, and setting forth no facts upon which a court could find a violation of the [law], fails to state a claim under Rule 12(b)(6).

In re Tamoxifen Citrate Antitrust Litig., supra, 466 F.3d at 200-201, 2006 U.S. App. LEXIS 22154 at *38-39 (some citations and quotations omitted).

Appendix B

Plaintiffs have failed to allege and plead sufficient facts indicating that Aventis participated in the prosecution of the '398 Patent, or that Aventis knew or subsequently learned of Ferring's inequitable conduct to obtain the '398 Patent. That Aventis would pay to license a patent which it knew to be unenforceable flies in the face of reason. That Aventis agreed with Ferring to participate in a scheme to exploit an unenforceable patent or that Aventis shared Ferring's allegedly anti-competitive intent also makes no sense. The pleadings against Aventis are threadbare, and as understandably argued by Aventis, implicate the traditional concerns that pleadings must provide a defendant with notice of a plaintiff's claim sufficient to answer and defend and of avoiding harassment and harm to a defendant's good will. Plaintiffs have failed to meet their burden of alleging sufficiently that Aventis had knowledge of an alleged fraud upon the PTO by Ferring.

Conclusions

The motions are granted. All claims pleaded under federal law are dismissed. The claims arising under state law are dismissed without prejudice. The Clerk shall file a final judgment.

SO ORDERED.

Dated: White Plains, New York
November 2, 2006

s/ Charles Brieant
Charles L. Brieant, U.S.D.J.

APPENDIX C — ORDER OF THE UNITED STATES COURT OF APPEALS FOR THE SECOND CIRCUIT DENYING PETITION FOR REHEARING FILED DECEMBER 29, 2009

UNITED STATES COURT OF APPEALS FOR THE SECOND CIRCUIT

06-5525-cv

In Re: DDAVP DIRECT PURCHASER ANTITRUST LITIGATION

MEIJER, INC., MEIJER DISTRIBUTION, INC., on behalf of themselves and all others similarly situated,

Plaintiffs-Appellants,

ROCHESTER DRUG CO-OPERATIVE, INC., LOUISIANA WHOLESALE DRUG CO., INC.,

Consolidated Plaintiffs-Appellants.

— v. —

FERRING B.V., FERRING PHARMACEUTICALS, INC., AVENTIS PHARMACEUTICALS, INC.,

Defendants-Appellees.

Appendix C

— v. —

VISTA HEALTHPLAN, INC., on behalf of itself and all others, PENNSYLVANIA EMPLOYEES BENEFIT TRUST FUND, on behalf of itself and all others, PAINTERS DISTRICT COUNCIL NO. 30 HEALTH AND WELFARE FUND, PHILADELPHIA FEDERATION OF TEACHERS HEALTH AND WELFARE FUND,

Consolidated Plaintiffs.

Ferring B.V., and Ferring Pharmaceuticals having filed a petition for panel rehearing, or, in the alternative, for rehearing *en banc*, and the panel that determined the appeal having considered the request for panel rehearing, and the active members of the Court having considered the request for rehearing *en banc*.

IT IS HEREBY ORDERED that the petition is denied.

For the Court
Catherine O'Hagan Wolfe, Clerk

By: s/ Frank Perez
Frank Perez, Deputy Clerk

APPENDIX D — CONSOLIDATED AMENDED CLASS ACTION COMPLAINT DATED MARCH 31, 2006

UNITED STATES DISTRICT COURT SOUTHERN DISTRICT OF NEW YORK

05 Civ. 2237 (CLB)

IN RE: DDAVP DIRECT PURCHASER ANTITRUST LITIGATION

This Document Relates To: All Actions

CONSOLIDATED AMENDED CLASS ACTION COMPLAINT

Plaintiffs Meijer, Inc., Meijer Distribution, Inc., Rochester Drug Co-operative, Inc., and Louisiana Wholesale Drug Company, Inc. bring this action on behalf of themselves and all others similarly situated against Defendants Ferring B.V., Ferring Pharmaceuticals, Inc., (collectively, "Ferring") and Aventis Pharmaceuticals, Inc. ("Aventis") (collectively, "Defendants"), to recover threefold damages, the costs of suit and reasonable attorneys' fees for injuries sustained by Plaintiffs resulting from Defendants' violations of Section 2 of the Sherman Act, 15 U.S.C. § 2. Plaintiffs make the following allegations based upon personal knowledge as to those matters relating to themselves and upon information and belief as to all other matters.

Appendix D

NATURE OF THE ACTION

1. This case arises from Defendants' unlawful scheme to maintain illegally their monopoly in the United States market for desmopressin acetate tablets. Defendants market desmopressin acetate tablets under the brand name DDAVP.

2. DDAVP is approved (1) as an anti-diuretic replacement therapy in the management of central diabetes insipidus and for the management of temporary polyuria (excessive urination) and polydipsia (excessive thirst) following head trauma or surgery in the pituitary region, and (2) for the management of primary nocturnal enuresis (bed wetting), when used either alone or an adjunct to behavioral, conditional, or other non-pharmacologic intervention. Desmopressin is also available in the form of intranasal sprays and injections.

3. As alleged more fully below, Defendants engaged in an exclusionary scheme to prevent and delay generic entry and to protect their monopoly in desmopressin acetate tablets. This scheme involved, *inter alia:* (1) procuring U.S. Patent No. 5,407,398 (the " '398 patent"), which claims desmopressin acetate tablets, by committing fraud and/or inequitable conduct on the United States Patent and Trademark Office ("PTO"); (2) improperly listing the fraudulently obtained '398 patent in the United States Food and Drug Administration ("FDA") publication known as the Orange Book; (3) filing and prosecuting sham patent infringement litigation against competitors to forestall

FDA approval of generic desmopressin acetate tablets; and (4) filing a sham citizen petition to further delay final FDA approval of generic desmopressin acetate tablets.

4. Absent Defendants' exclusionary scheme, less expensive generic versions of desmopressin acetate tablets would have been available in the market much earlier. Through their unlawful conduct, Defendants illegally deprived Plaintiffs (and the other direct purchasers who comprise the Class alleged herein) of access to substantially lower-priced generic versions of desmopressin acetate tablets, thereby causing Plaintiffs and other members of the Class to pay supra-competitive prices for DDAVP and its generic equivalents.

5. As a result of Defendants' illegal acts, Defendants have (1) unreasonably restrained, suppressed, and eliminated competition in the market for desmopressin acetate tablets; (2) illegally maintained monopoly power; (3) fixed, raised, maintained, and/or stabilized the price of desmopressin acetate tablets at supra-competitive levels; and (4) overcharged Plaintiffs and other members of the Class by hundreds of millions of dollars.

JURISDICTION AND VENUE

6. This action is brought under Section 4 of the Clayton Act, 15 U.S.C. § 15, to recover treble damages and the costs of suit, including reasonable attorneys' fees, for injuries sustained by Plaintiffs and members of the Class as a result of Defendants' violations of

Section 2 of the Sherman Act, 15 U.S.C. § 2, as alleged herein.

7. This Court has jurisdiction over the subject matter of this civil action pursuant to 28 U.S.C. §§ 1331 and 1337, and 15 U.S.C. § 15.

8. Venue is proper in this Court under 28 U.S.C. § 1391 and 15 U.S.C. § 22 because (1) Defendants transact business, committed an illegal or tortious act, and/or are found within this district; and (2) a substantial portion of the affected trade and commerce described below has been carried out in this district.

PARTIES

9. Plaintiffs Meijer, Inc. and Meijer Distribution, Inc. (collectively, "Meijer") are corporations organized and existing under the laws of the State of Michigan, with their principal place of business at 2929 Walker Avenue, NW, Grand Rapids, Michigan 49544. Meijer is the assignee of the claims of the Frank W. Kerr Co., which purchased DDAVP tablets directly from one or more of the Defendants during the Class Period, defined below.

10. Plaintiff Louisiana Wholesale Drug Company, Inc. ("Louisiana Wholesale") is a corporation organized and existing under the laws of the State of Louisiana and is located at 2085 I-49 South Service Road, Sunset, Louisiana 70584. Louisiana Wholesale purchased DDAVP tablets directly from one or more of the Defendants during the Class Period, defined below.

Appendix D

11. Plaintiff Rochester Drug Co-operative, Inc. ("RDC") is a drug wholesale cooperative located at 50 Jet View Drive, Rochester, New York 14624. RDC purchased DDAVP tablets directly from one or more of the Defendants during the Class Period, defined below.

12. Defendant Ferring B.V. is a privately-held company organized and existing under the laws of The Netherlands, with its principal place of business at Postbus 184, Hoofddorp NL-2130 AD, Netherlands.

13. Defendant Ferring Pharmaceuticals, Inc. (hereinafter referred to collectively with Ferring B.V. as "Ferring") is a New York corporation with its principal place of business at 400 Rella Boulevard, Suite 300, Suffern, New York. Ferring Pharmaceuticals, Inc. is a subsidiary of Defendant Ferring B.V. Ferring is the owner and assignee of the '398 patent.

14. Defendant Aventis Pharmaceuticals, Inc. ("Aventis") is a Delaware corporation with its principal place of business at 300 Somerset Corporate Boulevard, Bridgewater, New Jersey 08807. Aventis is the holder of an approved New Drug Application, No. 019-955, for desmopressin acetate tablets, which are marketed in the United States under the brand name DDAVP.

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CLASS ACTION

15. Plaintiffs bring this action under Rule 23 of the Federal Rules of Civil Procedure on behalf of themselves and the following class (the "Class"):

> All persons and entities in the United States that purchased DDAVP in tablet form directly from one or more of the Defendants at any time from February 18, 2001 through the date on which the anticompetitive effects of Defendants' conduct cease (the "Class Period"). Excluded from the Class are Defendants, their parents, subsidiaries and affiliates, employees, and federal government entities.

16. The Class is so numerous that joinder of all members is impracticable. Plaintiffs believe that the Class numbers one hundred or more. Further, the Class is readily identifiable from information and records in the possession, custody, or control of Defendants.

17. There are questions of law and fact common to the Class, including:

a. whether Defendants unlawfully maintained monopoly power by delaying generic entry;

b. whether market power in a relevant market is necessary to show a violation;

c. whether direct proof of Defendants' monopoly power is available, and if available, whether it is sufficient to prove Defendants' monopoly power without the need to also define a relevant market;

d. whether Defendants committed fraud and/or inequitable conduct on the PTO;

e. whether, but for Defendants' fraud, the '398 patent would not have issued;

f. whether the activities of Defendants as alleged herein have substantially affected interstate commerce;

g. whether Defendants' citizen petition was a sham and whether it caused common harm; and

h. whether, and to what extent, Defendants' conduct caused antitrust injury to the business or property of Plaintiffs and the members of the Class, and if so, the appropriate measure of damages.

These and other questions of law and fact are common to the members of the Class and predominate over any questions affecting only individual members.

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18. Plaintiffs' claims are typical of the claims of the Class because all Class members, including Plaintiffs, sustained antitrust injury in the same way as a result of Defendants' unlawful conduct, and the claims of each Class member arise out of the same nucleus of operative facts and are based on the same legal theories.

19. Plaintiffs will fairly and adequately represent and protect the interests of the Class. Plaintiffs have retained counsel who are experienced in class action and antitrust litigation, and Plaintiffs have no interest in this litigation that is adverse to, or in conflict with, the interests of the other members of the Class.

20. A class action is superior to other available methods for the fair and efficient adjudication of the controversy because such treatment will permit a large number of similarly situated persons to prosecute their common claims in a single forum simultaneously without the unnecessary duplication of evidence, effort, and expense that numerous individual actions would engender. The benefits of proceeding through the class mechanism, including providing injured persons or entities with a method for obtaining redress on claims that it might not be practicable to pursue individually, substantially outweigh any difficulties that may arise in management of this class action. Plaintiffs know of no difficulty that will be encountered in the management of the claims advanced by the Class that would preclude class certification.

Appendix D

BACKGROUND

The Regulatory System Governing Pharmaceuticals in the United States

21. The Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 *et seq.*, as amended by the Drug Price Competition and Patent Term Restoration Act of 1984 (the "Hatch-Waxman Act"), and the Medicare Prescription Drug, Improvement and Modernization Act of 2003, codified at 21 U.S.C. § 355(j) and 35 U.S.C. § 271(e) (2005), establishes procedures for obtaining approval to market pharmaceutical products in the United States.

22. A manufacturer seeking to market a new drug must file with the FDA a New Drug Application (NDA), demonstrating the safety and efficacy of its product. 21 U.S.C. § 355(b) (2005).

23. New drugs that are approved for sale in the United States by the FDA may be covered by one or more patents, which provide the patent owner with the right to seek to exclude others from making, using, and/or selling (depending on the scope of the patent) the new drug in the United States for the duration of the patents, plus any extension of the original patent period granted pursuant to the Hatch-Waxman Act described below.

24. Pursuant to 21 U.S.C. § 355(b), the applicant must list in the NDA any patents that claim the drug

for which FDA approval is being sought, or that claim a method of using the drug, and with respect to which a claim of patent infringement could reasonably be asserted against an unlicensed manufacturer or seller of the drug.

25. The FDA maintains a list of approved "Reference Listed Drugs" in a publication entitled, "Approved Drug Products with Therapeutic Equivalence Evaluations," which is commonly known as the "Orange Book." Once the FDA approves the NDA, the manufacturer may market the new branded drug, and the branded drug may be listed in the Orange Book, along with any patent that, according to the manufacturer, (1) claims either the approved drug or, in the case of a method-of-use patent, claims the approved use of the approved drug, and (2) with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug. 21 U.S.C. § 355(j)(7)(A)(iii).

26. Despite FDA regulations that limit the types of patents that NDA holders can list in the Orange Book, it has become common for brand companies to list any and every patent they can obtain in the Orange Book—regardless of the patent's scope or validity.

27. The FDA employs no adjudicatory or other process to determine whether a patent submitted by an NDA holder qualifies for listing under the applicable regulations. Because the FDA lacks the resources and

expertise to review the submitted patents, it must rely entirely on the good faith of the NDA holder submitting a patent for listing. *See* 59 Fed. Reg. 50,338, 50,343 (Oct. 3, 1994) ("FDA does not have the expertise to review patent information . . ."). As a result, courts recognize that the FDA's role in the patent listing process is purely ministerial.

Generic Drugs

28. Generic drugs are drugs that the FDA has found to be pharmaceutically equivalent and bioequivalent to a corresponding brand name drug. A drug is pharmaceutically equivalent compared with a brand name drug, if it contains the same active ingredient(s), is of the same dosage form, uses the same route of administration, is identical in strength and concentration, contains the same amount of active ingredient, and meets the same or compendial or other applicable standards. A drug is bioequivalent to a brand name drug if its active ingredient is absorbed at the same rate and to the same extent as the brand name drug.

29. Generic drugs are invariably priced substantially below the branded drugs to which they are pharmaceutically equivalent and bioequivalent. Typically, generic versions of brand name drugs are initially priced significantly below the brand name versions. As more generic manufacturers enter the market, prices for generic versions of a drug predictably plunge even further. This price competition enables all

direct purchasers of a drug to (a) purchase generic versions of the drug at substantially lower prices, and/or (b) purchase the brand name drug at a reduced price.

30. In 1984, Congress enacted the Hatch-Waxman Act, which accelerates the approval process for generic drugs. Among other things, it permits a manufacturer seeking FDA approval for a generic drug to file an Abbreviated New Drug Application ("ANDA"). 21 U.S.C. § 355(j) (2005). An ANDA filer may rely on the safety and efficacy data previously provided in the NDA for its branded counterpart. FDA approval of an ANDA takes, on average, about 18 to 20 months.

31. FDA-approved generic drugs are certified by the FDA as pharmaceutically equivalent and bioequivalent to the branded drug, and are completely interchangeable with that branded drug. The FDA refers to such drugs as "AB-rated." A generic drug that is "AB-rated" may be dispensed by a pharmacist in lieu of its branded counterpart.

32. At the same time, the Hatch-Waxman Act also provides the brand-name manufacturer with various means to maintain or extend the market exclusivity for a brand name drug. For example, Hatch-Waxman grants the NDA applicant that receives approval for a New Chemical Entity an extra five (5) year period of exclusivity to market that drug. 21 U.S.C. § 355(c)(3)(D)(ii) (the "NCE exclusivity"). Pursuant to Hatch-Waxman, the FDA may not accept and start reviewing an ANDA application relating to the brand

name product during the 5-year NCE exclusivity period, unless the ANDA includes a Paragraph IV certification (described in more detail below), in which case such an ANDA may be filed after only four (4) years of the NCE exclusivity period. *See* 21 U.S.C. § 355(j)(5)(D)(ii).

33. Hatch-Waxman also created a procedure by which a brand-name manufacturer can delay the final approval and market entry for a generic drug for up to thirty months while patent infringement issues are being litigated in the courts. If a patent for a brand-name drug is listed in the Orange Book, then any competitor seeking to sell a generic equivalent of the brand-name drug claimed by the listed patent, must include with its ANDA application one of the following four certifications regarding each listed patent:

a. a certification that no patent for the brand-name drug has been filed with the FDA (a "paragraph I certification");

b. a certification that the patent for the brand-name drug has expired (a "paragraph II certification");

c. a certification that the patent for the brand-name drug will expire on a particular date and the generic company does not seek to market its generic product before that date (a "paragraph III certification"); or

> d. a certification that the patent for the brand-name drug is invalid or will not be infringed by the generic manufacturer's proposed product (a "paragraph IV certification").

21 U.S.C. § 355(j)(2)(A)(vii).

34. If a generic manufacturer files with its ANDA a paragraph IV certification asserting that the patent listed in the Orange Book in connection with the brand-name drug is invalid or will not be infringed by the proposed generic product, the ANDA applicant must promptly give notice of this fact to both the NDA holder and the owner of the patent(s) at issue.

35. Filing a paragraph IV certification with the FDA constitutes a "technical act of infringement" under Hatch-Waxman, which creates jurisdiction in the federal courts to entertain a patent infringement action, and gives the NDA holder forty-five (45) days from the date of the notice to institute such an action against the generic manufacturer under 35 U.S.C. § 271(e)(2). *See* 21 U.S.C. § 355(j)(5)(B)(iii). If a patent infringement action is initiated, FDA approval of the ANDA is automatically stayed for up to thirty months. 21 U.S.C. § 355(j)(5)(B)(iii).

36. If the NDA holder fails to initiate a patent infringement action within 45 days after receiving the generic manufacturer's paragraph IV certification, then the FDA may finally approve the generic manufacturer's

ANDA once the FDA is satisfied that the generic is equivalent to the brand name drug. If, however, the NDA holder initiates an infringement action against the ANDA filer within 45 days, then the FDA may not finally approve the ANDA until the earlier of either 30 months or the issuance of a decision by a court that the patent is invalid or not infringed by the generic manufacturer's ANDA. 21 U.S.C. § 355(j)(5)(B)(iii). While the paragraph IV certification notice creates a jurisdictional basis for a patent infringement suit, an NDA holder cannot legitimately file a patent infringement claim against an ANDA applicant unless there is a legitimate factual and legal basis for such claim.

37. Moreover, if the NDA holder wishes to do so, it can refrain from filing a lawsuit within 45 days, wait for the generic to obtain final FDA approval and enter the market, and then file suit. Under those circumstances, the NDA holder would need to carry its normal burden to obtain a preliminary injunction against the generic company.

38. Brand-name manufacturers have a strong incentive to list any and every patent they can obtain in the Orange Book in order to trigger paragraph IV certifications and to file patent infringement suits against ANDA filers. There mere filing of an infringement action in response to a paragraph IV certification, regardless of the action's underlying merit, gives the brand-name company the functional equivalent of a self-effectuating preliminary injunction blocking the entry of a generic competitor. Indeed, as a practical

matter, the brand-name company wins the lawsuit simply by filing it because the filing automatically protects the company's monopoly for up to two-and-a-half years while the patent infringement action grinds through the court system.

39. An improper Orange Book listing also has additional anti-competitive effects because the first generic company to file an ANDA with a paragraph IV certification is, upon FDA approval, granted a 180-day period of exclusivity in relation to other generic manufacturers. 21 U.S.C. § 355(j)(5)(B)(iv). This 180-day exclusivity against other generic competitors is awarded to the first paragraph IV filer regardless of whether or not the brand company institutes pre-approval patent infringement litigation in response to the paragraph IV certification. Absent an improper Orange Book listing, no paragraph IV certification would be required, and thus, no generic company would receive 180-day exclusivity.

40. Defendants were at all times fully familiar with their ability to delay the entry of generic competition by the improper manipulation of the patent listing and pre-approval litigation provisions of the Hatch-Waxman Act.

Appendix D

DEFENDANTS' OVERARCHING SCHEME TO DELAY GENERIC ENTRY

41. In order to forestall competition and protect their monopoly, Defendants engaged in an unlawful, exclusionary scheme involving (1) fraud and/or inequitable conduct on the PTO; (2) improper Orange Book listings; (3) sham patent infringement litigation against competitors; and (4) a sham citizen petition filed with the FDA. Defendants' conduct as a whole resulted in an unlawful creation and extension of their monopoly in desmopressin acetate tablets.

Defendants Worked Closely Throughout the Overarching Scheme

42. For over three decades, Aventis (and/or its corporate predecessors) have had a close working relationship with Ferring. During this time, Aventis (and/or its corporate predecessors and subsidiaries) have acted as Ferring's partners and/or agents regarding the sale of desmopressin products in the United States and elsewhere. As Ferring states on its website regarding its "Current Partners":

> Commercial Partners
>
> The development from a small, research-driven pharmaceutical company in the 1950s into the global mid-sized pharmaceutical company that Ferring is today has been well supported by various commercial

partnerships. Some of Ferring's key commercial partnerships are:

Aventis has been marketing Ferring's flagship MINIRIN in the US since the 1970s.

Minirin is one of the brand names for Ferring's desmopressin products.

43. Ferring obtained Patent No. 3,454,549 (the " '549 Patent") in 1969 and Patent No. 3,497,491 (the " '491 Patent") in 1970. The '549 Patent claimed the compound and process of making a synthetic version of the naturally-occurring human hormone, vasopressin, which has an anti-diuretic effect. The '491 Patent claims the polypeptide of vasopressin functioning as a targeted anti-diuretic for the treatment of diabetes insipidus.

44. In 1977, Ferring received approval from the FDA to market an intranasal formulation of DDAVP as an anti-diuretic. Ferring exclusively licensed the right to market and sell its patented compound in the United States to Rorer, one of Aventis's corporate predecessors. In the late 1970s and/or early 1980s, Rorer filed an NDA to sell Ferring's DDAVP nasal solution in the United States. That NDA application was approved at some time prior to 1982, and sometime thereafter Rorer began selling in the United States a desmopressin nasal solution manufactured by Ferring.

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45. In the late 1970s and/or early 1980s, Rorer filed an NDA to sell an injectable form of Ferring's desmopressin product in the United States. That NDA application was approved on or about March 30, 1984, and sometime thereafter Rorer began selling in the United States an injectable form of desmopressin manufactured by Ferring.

46. During the 1980s, Ferring and Aventis's corporate predecessors sold tens of millions of dollars in desmopressin products in the United States. It was foreseeable to Ferring and Aventis's corporate predecessors that the revenues and profits from the injectable and nasal solution forms of DDAVP would fall substantially once generic forms of those products entered the market after the expiration of the patents.

47. In an apparent effort to either (a) offset the expected financial decline that would occur once Ferring's existing desmopressin products faced competition, and/or (b) generally increase their revenues and profits from desmopressin products, the Defendants undertook the scheme alleged herein, surrounding the development and marketing of a desmopressin acetate tablet. This scheme involved inequitable conduct and/or fraud on the PTO, improper Orange Book listings, sham litigation, and a sham citizen petition.

48. By 1989 — one year before the patents on the other desmopressin products expired — Ferring and Rorer had already submitted an NDA to obtain FDA approval for a desmopressin tablet. A tablet form of

desmopressin for swallowing has obvious and distinct advantages over other forms (such as a nasal spray) including greater convenience, ease of use and administration, elimination of unpleasant taste and smell, and consequent patient appeal and compliance. Such a tablet form of desmopressin would not be (and is not) AB-rated to non-tablet forms.

49. However, by this time Ferring's application for a U.S. patent that would claim desmopressin tablets had already been rejected twice. It was foreseeable to Defendants that if they did not receive a patent for desmopressin tablets, competitors would be able to sell their own or generic versions sooner than they would otherwise if patent protection was obtained. Thus, Defendants were willing to seek FDA approval to market desmopressin tablets without patent protection, but the prospect of such protection provided strong financial incentives for Defendants to obtain a patent by any means, including fraud.

Defendants Procure '398 Patent Through Fraud and/or Inequitable Conduct on the PTO

50. Rules governing patent prosecution impose a duty of candor and good faith on those dealing with the PTO, "which includes a duty to disclose to the Office all information known to that individual to be material to patentability as defined in this section." 37 C.F.R. § 1.56. The rule provides: "Information is material to patentability when it is not cumulative to information already of record or being made of record in the

application, and (1) It establishes, by itself or in combination with other information, a prima facie case of unpatentability of a claim; or (2) It refutes, or is inconsistent with, a position the applicant takes in: (i) Opposing an argument of unpatentability relied on by the Office, or (ii) Asserting an argument of patentability." Prior to 1992, the rule also provided that "information is material where there is a substantial likelihood that a reasonable examiner would consider it important in deciding whether to allow the application to issue as a patent." 37 C.F.R. § 1.56(a)(1991).

51. As explained more fully below, Ferring knowingly provided false and misleading information to the PTO in order to overcome the PTO's legitimate rejection of Ferring's attempt to claim an invention that was obvious and anticipated by the prior art.

52. On December 17, 1985, Ferring filed an application (serial no. 809,937) with the PTO that ultimately issued as the '398 patent (" '398 patent application"). The '398 patent application attempted to patent a gastro-intestinally absorbable form of DDAVP, *i.e.*, a tablet form of desmopressin acetate. If successful, the '398 patent application would have given Ferring renewed exclusivity in the sale of desmopressin products because Ferring would be the only company allowed to market the tablet form of desmopressin acetate.

53. The two inventors listed on the '398 patent application are Dr. Hans Vilhardt, a former research

director at Ferring, and Mr. Helmer Hagstam, who was then the technical director at Ferring. The inventors assigned their rights in the application to Ferring on May 21, 1984.

54. On May 28, 1986, Dr. Vilhardt and his attorney appeared at a preliminary interview with the PTO examiners to discuss the '398 patent application and prior art—in particular, U.S. Patent No. 3,497,491 ("Zaoral" or " '491 Patent") and U.S. Patent No. 3, 454,549 ("Boissanas" or " '549 Patent").

55. Ferring was the exclusive licensee of the Zaoral patent until its expiration in 1987. The Zaoral patent taught that "1-deamino-8-D-arginine vasopressin" "may be used . . . for . . . peroral . . . application." '491 Patent at col. 3 1.15-23, col. 5 1.15-20. The examiners were concerned that the Zaoral patent's disclosure of "peroral" (through the mouth) application of the peptide may have suggested the oral administration of the peptide for gastrointestinal absorption.

56. The examiner's written summary of the interview states that Dr. Vilhardt and his attorney argued to the examiner "that prior art does not teach administration via stomach route and that peroral implies 'buccal' [through the cheek] etc., and that one skilled in the art would not think otherwise." It also states that the applicants agreed to "consider amending the claims and filing declarations" and the examiner agreed to wait two weeks before giving a first action. The examiner also asked that the applicants to obtain

evidence from a non-inventor to show that the '398 patent was not obvious in light of the prior art.

57. The PTO examiners were aware that Ferring was the exclusive licensee of the '491 patent, which was soon to expire, and had an interest in convincing the PTO that the '398 patent application disclosed an invention not disclosed in the '491 patent. Therefore, they were concerned about the objectivity of those providing declarations and their relationship to Ferring.

58. Given the examiner's request for non-inventor declarations, Ferring was on notice that it needed to submit declarations from disinterested persons, and knew or should have known that a declarant's affiliations with the applicant were material.

59. On June 12, 1986, Ferring submitted a preliminary amendment with four declarations, including two from Vilhardt himself, one from Dr. Myron Miller, and one from Dr. Paul Czernichow. These declarations each relayed the declarant's scientific belief that the term "peroral" in the '491 patent meant that the compound could be administered "through the mouth," but only for absorption through the cheek (buccal) or under the tongue (sublingual).

60. Dr. Czernichow's declaration and accompanying curriculum vitae failed to disclose that he had received research funding from Ferring from 1985 to 1986 to conduct a clinical investigation relating to a particular DDAVP preparation.

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61. At some point during the '398 patent prosecution, Dr. Vilhardt also sought, but never submitted, declarations from two other Ferring consultants, Professor Leonard Share and Professor Besser.

62. Despite the four declarations submitted with Ferring's amendment, on November 20, 1986, the PTO rejected the '398 patent application as anticipated by or obvious in light of the Zaoral Patent. The rejection stated: "As Applicants are the exclusive licensee of the Zaoral patent, it is obviously expeditious for Applicants to argue that 'peroral' referred to in the [Zaoral] patent referred only to sublingual or buccal routes, whereas the instant mode of administration excludes such routes as it involves absorption by the gastrointestinal tract."

63. On May 20, 1987, Ferring filed a request for reconsideration, arguing that the '491 patent did not teach the claims of the '398 patent application.

64. On August 14, 1987, the PTO again rejected the '398 patent application based on prior art.

65. On September 21, 1990, the Board of Patent Appeals and Interferences affirmed the examiner's rejection of the '398 patent application, concluding that the "peroral" recitation in the '491 patent coupled with the knowledge of the prior art disclosed in a 1974 study conducted by Vavra was suggestive of and anticipated the oral administration of DDAVP for gastrointestinal absorption in humans. The Vavra study involved the

administration of desmopressin to rats by stomach gavage and showed that DDAVP caused antidiuresis in rats. However, because the examiners had not relied on the Vavra reference, the Board designated its decision as "a new rejection under the provisions of 37 C.F.R. § 1.196(b)," and explained that the applicant could elect to have further prosecution before the examiner in response to the new rejection.

66. On November 21, 1990, Ferring filed an Amendment after Appeal with the PTO. In support of its amendment, Ferring submitted declarations from Drs. Vilhardt, Miller, and Czernichow, as before, and from Dr. Ian Robinson and Dr. Tomislav Barth, to support its argument that the invention disclosed in the '398 patent application was not obvious despite the prior art. Each of these declarations explained why, in the declarant's own professional judgment, the Vavra reference did not suggest that DDAVP could be absorbed through the gastrointestinal tract.

67. Ferring did not disclose to the PTO that four of the five declarations submitted to the PTO were written by scientists who had been employed by, or had received research funds from Ferring. Nor did it disclose that Dr. Vilhardt had participated in the drafting of two of the four declarations submitted by non-inventors. The examiners were not and could not have otherwise been aware of the declarants' relationships with Ferring.

68. As with the declaration submitted with the first '398 patent application, Ferring did not inform the PTO of Dr. Czernichow's affiliation with Ferring.

69. Ferring failed to inform the PTO that Dr. Robinson (one of the new declarants): (1) had been Ferring's pre-clinical research director from 1985 to 1986; (2) had been a paid consultant for Ferring from 1986-1989; (3) while Robinson was the research director at Ferring, Ferring was funding Vilhardt's research involving DDAVP tablets; and (4) Ferring had sponsored a research program in Dr. Robinson's laboratory for about three years.

70. Ferring also did not tell the PTO that, at the time Dr. Robinson submitted his declaration, he had no expertise in DDAVP tablets, that he did not recall having done any research on drug delivery systems or on the absorption of peptides in the gastrointestinal tract—two issues central to understanding whether the '398 patent was obvious in light of the prior art—and that he did not understand why he was retained to provide a declaration on DDAVP tablets.

71. Ferring's documents identify Dr. Barth (another new declarant) as a Ferring consultant. However, Ferring did not submit Dr. Barth's CV with his declaration, and did not disclose that Dr. Barth worked on several projects funded by Ferring between 1984 and 1987, and that he worked intermittently with Vilhardt on some projects between 1988 and 2000.

72. Ferring knew that it should have revealed the declarants' relationships with Ferring and/or interest in the '398 patent application because the Manual of Patent Examining Procedure in effect at that time stated: "Affidavits or declarations should be scrutinized closely and the facts presented with care. The *affiant's or declarant's interest is a factor which may be considered.*" (emphasis added).

73. On April 8, 1991, — after three rejections — the PTO issued a Notice of Allowability, allowing the '398 patent to issue.

74. The declarations Ferring submitted in support of its '398 patent application were highly material, and the failure to disclose the relationship of the declarants with Ferring was likely done with an intent to deceive. Had the PTO examiners been aware of the relationships and affiliations of the declarants, they would not have accorded the declarations much weight, and the '398 patent would not have issued.

Defendants Improperly List The '398 Patent in the Orange Book

75. Ferring licensed to Aventis the right to market and sell the invention of the '398 patent.

76. Despite knowing that the '398 patent had been procured by fraud or inequitable conduct, Defendants caused the '398 patent to be listed in the Orange Book. The Orange Book listing for the '398 patent was

fraudulent because: (a) the fraudulently obtained, invalid '398 patent could not claim a tablet form of DDAVP, and (b) a claim of infringement of the fraudulently obtained, invalid '398 patent could not reasonably be asserted against a person who engaged in the unlicensed manufacture, use, or sale of the drug.

77. If the '398 patent had not issued, Defendants would not have been able to list it in the Orange Book, nor would Defendants have been able to file suit(s) for patent infringement against potential competitors. In that event, Defendants would not have been able to invoke the 30-month stay of Hatch-Waxman.

78. Furthermore, absent the fraudulent Orange Book listing, none of the generic competitors would have filed Paragraph IV certifications regarding the '398 patent, and thus: (a) there would be no 180-day exclusivity for the first ANDA applicant; and (b) multiple generic competitors would have been able to enter the market at or about the same time, rather than having to wait for the 180-day exclusivity to expire.

79. As a result of the Orange Book listing, no generic manufacturer could submit an ANDA to the FDA, seeking approval to market a generic version of DDAVP in the United States without certifying either that its product would not be marketed in the United States until the expiration of each listed patent (paragraph III certification) or that each listed patent was invalid or not infringed by the proposed product (paragraph IV certification).

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80. Before Ferring had obtained a patent for desmopressin acetate tablets, Aventis had filed an NDA with the FDA for approval of that product. Once the '398 patent issued, Aventis amended its NDA to add a false and fraudulent Orange Book listing certification relating to the '398 patent.

81. Given the long and close business relationship among Defendants, including with respect to DDAVP, Ferring knew or likely knew about Aventis's actions regarding the NDA application and the Orange Book listing. Because Ferring knew that the '398 patent had been obtained fraudulently, Ferring therefore also knew or likely knew that Aventis's representations to the FDA regarding the listing of the '398 patent in the Orange Book were also false and misleading, for the reasons alleged herein.

82. The FDA approved Aventis's NDA on September 6, 1995. Shortly thereafter, Aventis began marketing desmopressin acetate tablets under the brand name DDAVP. Aventis's U.S. sales of DDAVP tablets were approximately $78 million in 2000, $98 million in 2001, $125 million in 2002, $157 million in 2003, and $180 million in 2004.

83. In the absence of the fraudulently obtained '398 patent, other pharmaceutical companies could have sought and obtained FDA approval for their own versions of desmopressin tablets without having to undertake the burden and expense of investigating the '398 patent and being sued for patent infringement.

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84. In the absence of the fraudulently or inequitably obtained '398 patent, and in light of existing sales of non-tablet forms of desmopressin (more than $70 million in 1995), one or more other pharmaceutical companies likely would have launched their own competing desmopressin tablets to compete with Defendants' DDAVP tablets, via, for example, an ANDA paragraph I certification.

85. By obtaining the '398 patent through fraud, Defendants eliminated this avenue of competition and forced potential competitors to, instead, undertake the burden and expense of investigating and challenging the '398 patent, via an ANDA paragraph IV certification and concomitant patent litigation, if they wished to sell desmopressin tablets before expiration of the '398 patent.

Defendants File Sham Litigation

Barr Litigation

86. In July 2002, Barr Laboratories, Inc. ("Barr") submitted to the FDA ANDA No. 76-470 to obtain approval to market a generic version of 0.1 and 0.2 mg DDAVP tablets. Barr's ANDA contained a paragraph IV certification that the '398 patent is invalid, unenforceable, and/or would not be infringed by Barr's generic product.

87. On or about October 29, 2002, Barr sent Defendants notice that Barr's ANDA had been received by the FDA and that the ANDA contained a paragraph IV certification.

88. On December 13, 2002, Defendants filed a patent infringement action against Barr in the United States District Court for the Southern District of New York. As Defendants had intended because they listed the '398 patent in the Orange Book, their patent infringement suit against Barr resulted in an automatic 30-month stay of final FDA approval of Barr's ANDA. Barr could not receive final FDA approval until it either prevailed in the patent infringement suit, or the expiration of thirty months, whichever occurred first. Thus, the mere filing of Defendants' sham lawsuit prevented a generic form of desmopressin acetate tablets from entering the market, thereby illegally extending Defendants' monopoly.

89. At the time Defendants' filed their infringement action against Barr, they knew that a claim of infringement could not be reasonably asserted against a person who engaged in the unlicensed manufacture, use, or sale of the drug because they knew the patent was invalid, unenforceable, and/or that it had been obtained through fraud and/or inequitable conduct.

90. On February 7, 2005, the United States District Court for the Southern District of New York granted summary judgment to Barr, holding that Ferring had committed inequitable conduct by deliberately deceiving the PTO about the non-inventor declarations submitted with the '398 patent application. The court found "clear and convincing evidence of an intent to mislead the examiners" and that "the deceit was practiced over a long period of time by more than one person and

appears to have been outcome determinative." *See Ferring B.V. v. Barr Labs., Inc.*, No. 02 Civ. 9851, 2005 WL 437981, at *10 (S.D.N.Y. Feb. 7, 2005). On the key issue of "but for" causation, the court found that "the PTO must have relied substantially on these declarations, as there is no alternative explanation offered for the Board's final allowance of the claims after several prior rejections by the PTO." *Id.* at *9-10. The District Court opinion was the first finding that Defendants had committed fraud on the PTO in obtaining the '398 patent and it publicly revealed Defendants' anticompetitive conduct.

91. On February 15, 2006, the United States Court of Appeals for the Federal Circuit affirmed the district court's grant of summary judgment on the issue of inequitable conduct. First, the Federal Circuit held that Defendants' failure to disclose the relationships between the "non-inventor" declarants and Ferring was "highly material as a matter of law" because the PTO examiners had specifically requested "non-inventor" affidavits and had expressly stated that they were concerned about the objectivity of those trying to distinguish the '491 patent from the invention claimed in the '398 patent application. *Ferring B.V. v. Barr Labs., Inc.*, 437 F.3d 1181, 1189-90 (Fed. Cir. Feb. 15, 2006). Second, the court found that the omission was made with the intent to deceive because the record established that the applicant knew of the information (i.e., relationships with Ferring), the applicant knew or should have known of the materiality of that information, and the applicant had not provided a credible explanation for the

withholding. The court concluded that "at least where the objectivity of the declarant is an issue in the prosecution [of the patent], the inventor must disclose the known relationships and affiliations of the declarants so that those interests can be considered in weighing the declarations." *Id.* at 1195.

92. By suing Barr under the Hatch-Waxman Act, Defendants delayed FDA approval of generic desmopressin acetate tablets by (1) provoking, in effect, a moratorium or a slow track on the FDA's consideration of Barr's ANDA and/or (2) undermining Barr's vigorous pursuit of its application.

93. The FDA receives numerous ANDAs per year and prioritizes those drug applications that are not subject to patent litigation. In the absence of Defendants' sham litigation, the FDA would have focused more attention on Barr's ANDA and would have granted approval earlier than July 1, 2005.

94. In addition, the sham litigation forced Barr to divert resources away from the FDA approval process and towards defending itself against Defendants' claims of patent infringement and undermined incentives to obtain rapid FDA approval since, for example, the 30-month stay under the Hatch-Waxman Act had been triggered.

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Teva Litigation

95. Sometime after July 2002, Teva Pharmaceuticals USA, Inc. ("Teva") also submitted an ANDA application to the FDA to sell a generic version of desmopressin acetate tablets.

96. On or about June 9, 2004, Ferring received notice that Teva had filed an ANDA with a paragraph IV certification seeking to market a generic version of desmopressin acetate tablets.

97. On July 20, 2004, Defendants filed a patent infringement action against Teva in the United States District Court for the District of Delaware. As with the Barr litigation, Defendants commenced and maintained this lawsuit even though it was (1) objectively baseless, in that no reasonable litigant could ultimately expect success on the merits given Defendants' fraud and/or inequitable conduct on the PTO; and (2) motivated by a desire to impose injury on Teva, a potential competitor, rather than to obtain justifiable legal relief.

98. By suing Teva under the Hatch-Waxman Act, Defendants delayed FDA approval of generic desmopressin acetate tablets by (1) provoking, in effect, a moratorium or a slow track on the FDA's consideration of Teva's ANDA and/or (2) undermining Teva's vigorous pursuit of its application.

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Defendants Use A Sham Citizen Petition To Further Delay Generic Entry

99. Under the citizen petition process, anyone may request or petition the FDA to change or create an agency policy or regulation under 21 C.F.R. Part 10.30. The FDA must respond within 180 days by either approving or denying the petition or by providing a tentative response indicating why it has been unable to reach a decision.

100. The citizen petition process may slow down approval of a drug because the FDA customarily evaluates an ANDA and a related citizen petition at the same time. The FDA is reluctant to approve a generic drug ANDA before acting on a citizen petition addressing the particular ANDA.

101. FDA regulations require that the party submitting the citizen petition certify that the petition "includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioner which are unfavorable to the petition."

102. Recently, the FDA's Chief Counsel, Sheldon Bradshaw, sought industry suggestions on the citizen petition process at the first annual Generic Pharmaceutical Association Law and Policy Conference in Washington, D.C. on September 19, 2005. Bradshaw stated that "[o]ne of the things [he had] learned in [his] short time at the agency is that there's been a bit of a

breakdown in this citizen petition process." Bradshaw observed that some citizen petitions seemed designed not to bring timely scientific or regulatory concerns to the agency's attention, but rather to delay action on a competitor's drug product by forcing the FDA to take time to analyze the issues raised in the petition when those issues are either not new or have been known to the petitioner for years before filing the petition.

103. One suggestion that has been made by the Generic Pharmaceutical Association is to separate the generic drug approval process from the process for ruling on citizen petitions in order to remove the incentive for filing frivolous petitions.

104. In early 2004, Defendants' patent infringement action against Barr was entering the summary judgment stage. Because Defendants had no objectively reasonable basis for filing the infringement action and their only intent in filing that action was to delay generic entry, Defendants likely knew or reasonably should have known that the district court would rule in favor of Barr, thus paving the way for FDA approval of Barr's ANDA.

105. In order to further delay FDA approval, Ferring filed a sham citizen petition on February 2, 2004 (Docket No. 2004P-0068/CP1). Ferring did not have a reasonable basis for filing the petition, and its only purpose and intent was to delay the entry of generic competitors into the market. Furthermore, Ferring's use of the citizen petition was an attempt to interfere directly with the business relationships of their generic

competitors through the use of governmental process — as opposed to the outcome of that process — as an anticompetitive weapon. At all relevant times, Defendants were aware that they could delay approval of Barr's generic ANDA by filing a citizen petition relating to ANDAs for oral desmopressin tablets.

106. Ferring wanted the FDA to require Barr to conduct and submit more tests — pharmacodynamic ("PD") studies measuring urine osmolarity — in order for Barr to establish the bioequivalence of Barr's desmopressin product to DDAVP. These new studies would have been in addition to the conventional pharmacokinetic (PK) tests measuring blood plasma concentration which Barr had already submitted to the FDA. In Ferring's purported opinion, the conventional PK bioequivalence tests did not adequately address safety and efficacy of oral desmopressin therapy for nocturnal enuresis in children. Thus, in its citizen petition, Ferring requested that ANDAs for generic oral desmopressin products include: (1) evidence from comparative clinical studies demonstrating bioequivalence to DDAVP in terms of both conventional PK blood plasma concentration measurements, as well as studying PD properties by measurement of urine osmolarity and flow rates in water-loaded enuretic (bed wetting) children; (2) if bioequivalence was not established by such PK and PD studies, evidence from comparative clinical trials demonstrating safety and efficacy equivalent to DDAVP in enuretic children; and (3) separate bioequivalence evidence for each dose level.

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107. In support of its petition, Ferring cited to several allegedly unique aspects of the drug, including (1) novel issues regarding variations in bioavailability, such as low effective plasma concentrations and high inter- and intra-subject variability; and (2) the fact the drug was intended for use in children, making the data from adults, purportedly insufficient to establish safety and efficacy.

108. As reflected in the FDA's rejection of the petition, discussed more fully below, Ferring's arguments had no basis in science, fact, FDA regulations or Guidance. The only goal in submitting the citizen petition was to preserve Defendants' monopoly in desmopressin acetate tablets. Given the FDA's limited resources and competing priorities, it was foreseeable or likely that even a frivolous citizen petition would cause delay. Indeed, on July 30, 2004, the FDA informed Ferring that it "ha[d] been unable to reach a decision on [its] petition due to the need to address other Agency priorities" and that the FDA would respond "as soon as possible given the numerous demands on the Agency's resources."

109. Ferring's citizen petition certified "that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioner which are unfavorable to the petition."

110. Nonetheless, the petition did not include information from a study sponsored by Defendant Aventis, which was unfavorable to the positions advanced by the petition. *See* Argenti, D., et al., *A Pharmacokinetic and Pharmacodynamic Comparison of Desmopressin Administered as Whole, Chewed, and Crushed Tablets, and as an Oral Solution*, J. Urology, Vol. 165, 1446 (May 2001) (the "Aventis Study").

111. The Aventis Study results demonstrated that, regardless of the formulation of desmopressin tested, the PK and PD responses observed were very similar. Thus, the type of tests which Ferring sought to require Barr to conduct would have been redundant at best, and caused needless delay in the approval of Barr's ANDA.

112. Ferring knew or should have known of the Aventis Study and yet did not disclose it in the citizens petition to the FDA. Aventis knew of its study and knew or should have known that the citizens petition was being filed without citing the Aventis Study, and yet let Ferring omit the Aventis Study from the citizens petition.

113. After the district court's grant of summary judgment to Barr in the patent litigation, on March 8, 2005, Barr submitted a response to the lengthy citizen petition, addressing each of the issues Ferring had raised. Barr pointed out that the "FDA repeatedly has affirmed that PK studies are the gold standard for establishing bioequivalence, particularly for orally

administered, systematically acting drug products, such as desmopressin." Barr also called the Aventis Study to the attention of the FDA, and stated that the "results [of the Aventis Study] explain why Ferring, and not the NDA-holder Aventis, submitted the instant citizen petition."

114. In its regulations, the FDA lists "in descending order of accuracy, sensitivity and reproducibility" the types of evidence that the agency will accept to establish bioequivalence. 21 C.F.R. § 320.24(b). The first and best option is a PK study, such as the one Barr had already included in its ANDA. According to the FDA's hierarchy of tests, the studies suggested by Ferring are the least accurate, sensitive, and reproducible tests of all.

115. On July 1, 2005, the FDA rejected Ferring's citizen petition, stating that Ferring had "offer[ed] no convincing evidence (i.e. data or other information) that any of your proposed changes are needed. ***Accordingly, not having been presented with any basis for departing from our long-established and well-settled practice, we deny your petition in its entirety.***" (emphasis added). The FDA also discussed each of Ferring's baseless claims, rejecting each in turn.

116. First, the FDA found no additional studies beyond conventional PK studies were required to be submitted with Barr's ANDA. The FDA concluded that "in the case of products like oral demopressin that are intended for systemic distribution within the body, and for which drug concentration levels can be measured in

blood plasma, the additional data [Ferring] request[ed] would be expected to be ***inferior*** to the measurement of plasma drug levels for establishing BE. [Ferring] fail[ed] to present . . . evidence either to refute this conclusion as to the additional data's inferiority, to demonstrate that conventional BE testing is inadequate, or to show that its augmentation by the additional data would enable more accurate determination of BE for generic oral desmopressin products than would conventional testing alone." (italics in original). Furthermore, the FDA found that it would expect that the duration of clinically significant action between DDAVP tablets and Barr's generic desmopressin tablets would be the same. Ferring "presented no evidence to refute this conclusion" and the FDA saw "no substantiated reason to believe" Ferring's argument regarding length of action.

117. Second, the FDA rejected Ferring's request for additional tests on children because Ferring had "articulated no scientifically substantiated reason — nor [was the FDA] aware of any, based on available data concerning desmopressin and other drugs — why a generic oral desmopressin product shown to be bioequivalent to DDAVP in healthy adults would not be bioequivalent to this [reference listed drug] in the approved pediatric population."

118. Finally, the FDA concluded there was no need for separate bioequivalence evidence for each dose level because "the data in DDAVP's NDA failed to adequately test, let alone demonstrate, a lack of proportionality in

drug exposure between the two strengths of DDAVP, and [Ferring had] not provided (nor [was the FDA] aware of) other data demonstrating such a lack of proportionality." The FDA generally waives studies for the lower strength if bioequivalence is established for the higher strength.

119. The FDA repeatedly cited the Aventis Study in its response to support its conclusion that Ferring's request for additional data was baseless. The FDA noted that although Ferring was required to attest that it had included information known to be unfavorable to the petition:

> Notably, the Petition also fail[ed] to disclose or describe a published study conducted by Aventis, the sponsor of the DDAVP NDA, on various desmopressin formulations that appears inconsistent with [Ferring's] position that pharmacodynamic or other clinical studies are needed to establish the [bioequivalence] of oral desmopressin products (. . . this study also appears inconsistent with [Ferring's] position in other respects). The Petition, in fact, does not cite any studies unfavorable to [Ferring's] arguments.

120. Ferring's omission of the Aventis Study is further evidence that the citizen petition was a sham.

121. On July 1, 2005 — the same day the FDA rejected Ferring's citizen petition — the FDA granted final approval of Barr's ANDA for generic desmopressin tablets. Absent Ferring's sham citizen petition, the FDA would have approved Barr's ANDA at an earlier date.

122. On July 15, 2005, Barr launched its generic version of desmopressin acetate tablets although Defendants' patent suit remained pending. Because Barr was the first ANDA filer, under Hatch-Waxman, it received a 180-day exclusivity period. Thus, as a result of Defendants' anticompetitive conduct described above, no other generic manufacturers could enter the market until Barr's exclusivity period had run.

123. On January 25, 2006, the FDA approved Teva's ANDA, and Teva began selling generic desmopressin tablets in January 2006. Teva, too, launched while the patent litigation was still pending.

124. On March 7, 2006, the FDA approved Apotex's ANDA, seeking to market a generic version of desmopressin acetate tablets. Apotex's market entry is expected shortly.

125. But for Defendants' illegal conduct, generic competitors would have begun marketing generic versions of DDAVP tablets much earlier.

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MONOPOLY POWER

126. Defendants have monopoly power with respect to DDAVP tablets and its AB-rated generic equivalents. Insofar as proof of a relevant market is required, the relevant product market is desmopressin acetate tablets and any AB-rated generic equivalents.

127. A significant non-transitory price increase for desmopressin acetate tablet products would not have caused significant loss of sales to non-desmopressin acetate tablet products.

128. The relevant geographic market is the United States and its territories.

129. Defendants' actions as part of, and in furtherance of, the illegal monopolization alleged herein, were authorized, ordered, or done by Defendants' officers, agents, employees, or representatives while actively engaged in the management of Defendants' affairs.

130. Defendants' illegal acts to prevent the introduction into the U.S. marketplace of any generic versions of DDAVP tablets resulted in Plaintiffs and members of the Class paying more than they would have paid for desmopressin tablets absent Defendants' illegal conduct. But for Defendants' illegal conduct, generic competitors would have begun marketing generic versions of DDAVP tablets much earlier.

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ANTICOMPETITIVE EFFECTS

131. Defendants' exclusionary conduct has enhanced and maintained Defendants' monopoly power by preventing generic entry into the relevant market and unlawfully enabled Defendants to sell DDAVP tablets without being subject to generic competition.

132. If generic competitors had been able to enter the market sooner, Plaintiff and other members of the Class would have purchased approved generics instead of the higher-priced brand-name drug for some or all of their desmopressin acetate tablet requirements and would have received discounts and/or have paid lower prices for some or all of any branded DDAVP tablet purchases. By preventing generic competitors from entering the market, Defendants caused Plaintiffs and other direct purchasers of DDAVP tablets to pay more for desmopressin acetate tablets than they otherwise would have.

133. Defendants' unlawful conduct, as alleged herein, not only caused delay in generic entry but delay in competition among generics. Absent Defendants' obtaining the '398 patent through fraud and/or inequitable conduct, fraudulent orange book listing, sham litigation and sham citizen petition, a generic desmopressin tablet would have received approval earlier, and any 180-day exclusivity period under Hatch-Waxman would have expired earlier than it did (or never would have been available at all). Had other generic competitors (such as Teva and Apotex) been able to

compete with their generic products sooner, the average price of desmopressin acetate tablets would have declined even further and more quickly.

DAMAGES

134. During the relevant period, Plaintiffs and members of the Class purchased substantial amounts of DDAVP tablets from one or more of the Defendants. As a result of the illegal conduct of Defendants, members of the Class were compelled to pay, and did pay, artificially inflated prices for their desmopressin acetate tablet requirements. Those prices were substantially greater than the prices that members of the Class would have paid absent the illegal conduct alleged herein, because: (1) the price of the brand-name desmopressin acetate tablets was artificially inflated or maintained by Defendants' illegal conduct; and/or (2) class members were deprived of the opportunity to purchase lower-priced generic versions of desmopressin acetate tablets. As a consequence, members of the Class have sustained substantial losses and damage to their business and property in the form of overcharges.

INTERSTATE TRADE AND COMMERCE

135. During all or part of the Class Period, one or more Defendants manufactured and sold substantial amounts of DDAVP in a continuous and uninterrupted flow of commerce across state and national lines and throughout the United States.

136. At all relevant times, DDAVP manufactured and sold by one or more Defendants was shipped across state lines and sold to customers located outside its state of manufacture.

137. During all or part of the Class Period, Defendants transmitted funds as well as contracts, invoices, and other forms of business communications and transactions in a continuous and uninterrupted flow of commerce across state and national lines in connection with the sale of DDAVP.

138. In furtherance of its efforts to monopolize and/or restrain competition in the market for DDAVP and its generic equivalents, Defendants employed the United States mails and interstate and international telephone lines, as well as means of interstate and international travel.

139. Defendants' efforts to monopolize and restrain competition in the market for DDAVP has substantially affected interstate and foreign commerce.

VIOLATIONS

Monopolization in Violation of Section 2 of the Sherman Act, 15 U.S.C. §2

140. Plaintiffs reallege and incorporate by reference all preceding paragraphs as if fully set forth herein.

141. At all relevant times, Defendants possessed monopoly power over the price of desmopressin acetate tablets in the United States. To the extent required by law, the relevant product market is desmopressin acetate tablets.

142. As a result of their monopoly power, Defendants have charged prices for desmopressin acetate tablets well above competitive prices. But for Defendants' exclusionary and anticompetitive conduct, as alleged herein, Defendants would not have created or maintained monopoly power.

143. Ferring and Aventis worked closely and in concert throughout the anticompetitive scheme alleged herein to create or maintain their monopoly power in the desmopressin acetate tablet market. Ferring and Aventis, singularly and jointly, each actively participated in all or most of the components of the exclusionary scheme alleged herein, and each benefited (and continued to benefit) from the scheme as alleged herein. Each acted in furtherance of the exclusionary scheme with the knowledge, assistance, and/or acquiescence of the other.

144. During the relevant period, Defendants knowingly, willfully, and unlawfully created and maintained their monopoly power by engaging in exclusionary conduct that discouraged rather than encouraged competition on the merits. As explained in detail above, Defendants engaged in an exclusionary scheme that included, *inter alia*, the following conduct:

a. Procuring the '398 patent by committing fraud and/or inequitable conduct before the PTO;

b. Improperly listing the fraudulently obtained '398 patent in the Orange Book;

c. Filing sham patent litigation against generic competitors in order to "trigger" the Hatch-Waxman automatic 30-month stay of FDA approval of the generic ANDAs; and

d. Filing a sham citizen petition to further delay FDA final approval of Barr's ANDA.

145. The goal, purpose, and/or effect of Defendants' scheme was to prevent, delay, and/or minimize the success of the entry of generic desmopressin acetate tablets. Generic desmopressin acetate tablets would have entered the market at prices significantly below Defendants' prices for DDAVP, which would have effectively caused the average market price of desmopressin acetate to decline dramatically.

146. The goal, purpose, and/or effect of Defendants' scheme was also to create, maintain, and extend Defendants' monopoly power with respect to desmopressin acetate tablets. Defendants' illegal scheme to prevent, delay, and/or minimize the success of the introduction into the United States marketplace

of any generic version of DDAVP enable Defendants to continue charging supracompetitive prices for desmopressin acetate tablets without a substantial loss of sales.

147. Plaintiffs and members of the Class have been injured in their business and property by reason of Defendants' antitrust violations. Their injury consists of paying higher prices for desmopressin acetate tablets than they would have paid in the absence of those violations. Such injury, namely overcharges, is of the type antitrust laws were designed to prevent and flows from that which makes Defendants' conduct unlawful.

JURY TRIAL DEMANDED

148. Plaintiffs demand trial by jury on all issues so triable.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs, on behalf of themselves and members of the Class, respectfully request:

(i) Certification of this case as a class action;

(ii) Judgment declaring Defendants' actions as alleged herein to be a violation of Section 2 of the Sherman Act;

(iii) Judgment in favor of Plaintiffs and members of the Class against Defendants for damages representing three times the overcharge damages sustained by Plaintiff and other members of the Class;

(iv) Joint and several judgment be entered against each Defendants in favor of Plaintiffs and the other members of the Class;

(v) Pre- and post-judgment interest;

(vi) Costs of suit, including reasonable attorneys' fees; and

(vii) Such other and further relief as the Court deems just and proper.

Dated: March 31, 2006

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APPENDIX E — RELEVANT STATUTES

28 USCS § 1295

§ 1295. Jurisdiction of the United States Court of Appeals for the Federal Circuit

(a) The United States Court of Appeals for the Federal Circuit shall have exclusive jurisdiction—

> (1) of an appeal from a final decision of a district court of the United States, the United States District Court for the District of the Canal Zone, the District Court of Guam, the District Court of the Virgin Islands, or the District Court for the Northern Mariana Islands, if the jurisdiction of that court was based, in whole or in part, on section 1338 of this title, except that a case involving a claim arising under any Act of Congress relating to copyrights, exclusive rights in mask works, or trademarks and no other claims under section 1338(a) shall be governed by sections 1291, 1292, and 1294 of this title;
>
> (2) of an appeal from a final decision of a district court of the United States, the United States District Court for the District of the Canal Zone, the District Court of Guam, the District Court of the Virgin Islands, or the District Court for the Northern Mariana Islands, if the jurisdiction of that court was based, in whole or in part, on section 1346 of this title, except that jurisdiction of an appeal

in a case brought in a district court under section 1346(a)(1), 1346(b), 1346(e), or 1346(f) of this title or under section 1346(a)(2) when the claim is founded upon an Act of Congress or a regulation of an executive department providing for internal revenue shall be governed by sections 1291, 1292, and 1294 of this title;

(3) of an appeal from a final decision of the United States Claims Court of Federal Claims;

(4) of an appeal from a decision of—

(A) the Board of Patent Appeals and Interferences of the United States Patent and Trademark Office with respect to patent applications and interferences, at the instance of an applicant for a patent or any party to a patent interference, and any such appeal shall waive the right of such applicant or party to proceed under section 145 or 146 of title 35;

(B) the Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office or the Trademark Trial and Appeal Board

with respect to applications for registration of marks and other proceedings as provided in section 21 of the Trademark Act of 1946 (15 U.S.C. 1071); or

(C) a district court to which a case was directed pursuant to section 145, 146, or 154(b) of title 35;

(5) of an appeal from a final decision of the United States Court of International Trade;

(6) to review the final determinations of the United States International Trade Commission relating to unfair practices in import trade, made under section 337 of the Tariff Act of 1930 (19 U.S.C. 1337);

(7) to review, by appeal on questions of law only, findings of the Secretary of Commerce under U.S. note 6 to subchapter X of chapter 98 of the Harmonized Tariff Schedule of the United States (relating to importation of instruments or apparatus);

(8) of an appeal under section 71 of the Plant Variety Protection Act (7 U.S.C. 2461);

(9) of an appeal from a final order or final decision of the Merit Systems Protection Board, pursuant to sections 7703(b)(1) and 7703(d) of title 5;

(10) of an appeal from a final decision of an agency board of contract appeals pursuant to section 8(g)(1) of the Contract Disputes Act of 1978 (41 U.S.C. 607(g)(1));

(11) of an appeal under section 211 of the Economic Stabilization Act of 1970;

(12) of an appeal under section 5 of the Emergency Petroleum Allocation Act of 1973;

(13) of an appeal under section 506(c) of the Natural Gas Policy Act of 1978; and

(14) of an appeal under section 523 of the Energy Policy and Conservation Act .

(b) The head of any executive department or agency may, with the approval of the Attorney General, refer to the Court of Appeals for the Federal Circuit for judicial review any final decision rendered by a board of contract appeals pursuant to the terms of any contract with the United States awarded by that department or agency which the head of such department or agency has concluded is not entitled to finality pursuant to the review standards specified in section 10(b) of the Contract Disputes Act of 1978 (41 U.S.C. 609(b)). The

head of each executive department or agency shall make any referral under this section within one hundred and twenty days after the receipt of a copy of the final appeal decision.

(c) The Court of Appeals for the Federal Circuit shall review the matter referred in accordance with the standards specified in section 10(b) of the Contract Disputes Act of 1978. The court shall proceed with judicial review on the administrative record made before the board of contract appeals on matters so referred as in other cases pending in such court, shall determine the issue of finality of the appeal decision, and shall, if appropriate, render judgment thereon, or remand the matter to any administrative or executive body or official with such direction as it may deem proper and just.

Appendix E

28 USCS § 1338

§ 1338. Patents, plant variety protection, copyrights, mask works, designs, trademarks, and unfair competition

(a) The district courts shall have original jurisdiction of any civil action arising under any Act of Congress relating to patents, plant variety protection, copyrights and trademarks. Such jurisdiction shall be exclusive of the courts of the states in patent, plant variety protection and copyright cases.

(b) The district courts shall have original jurisdiction of any civil action asserting a claim of unfair competition when joined with a substantial and related claim under the copyright, patent, plant variety protection or trademark laws.

(c) Subsections (a) and (b) apply to exclusive rights in mask works under chapter 9 of title 17, and to exclusive rights in designs under chapter 13 of title 17, to the same extent as such subsections apply to copyrights.